EFFECTIVENESS OF ORAL GLUCOSE ON PAIN RESPONSE AMONG INFANTS DURING INVASIVE PROCEDURES, IN PAEDIATRIC OUTPATIENT DEPARTMENT, GOVERNMENT RAJAJI HOSPITAL, MADURAI.

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CERTIFICATE

*This is to certify that this dissertation titled, "**Effectiveness of oral glucose on pain response among infants during invasive procedures, in paediatric outpatient department, Government Rajaji Hospital, Madurai."** Is a bonafide work done by **Mrs.Saranya.P** College of Nursing, Madurai Medical College, Madurai-20, submitted to THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY , Chennai in partial fulfillment of the university rules and regulations towards the award of the degree of **MASTER OF SCIENCE IN NURSING , Branch II, Child Health Nur**sing Under our guidance and supervision during the academic period from 2012-2014.*

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ABSTRACT

EFFECTIVENESS OF ORAL GLUCOSE ON PAIN RESPONSE AMONG INFANTS DURING INVASIVE PROCEDURES, IN PAEDIATRIC OUTPATIENT DEPARTMENT, GOVERNMENT RAJAJI HOSPITAL, MADURAI.

Objectives: The main objective of the study was to evaluate the effectiveness of oral glucose on pain response among infants during invasive procedure, paediatric outpatient department, Government Rajaji Hospital, Madurai. **Conceptual Framework:** Conceptual framework on modified general system theory by Ludwig Von Bertanffy. **Design**: This study employed Quasi experimental design. **Setting of the Study:** The study was conducted at paediatric outpatient department, Institute of Child Health and Research Centre, Government Rajaji Hospital, Madurai. **Subjects:** A total of 60 subjects were included in the study (30 in experimental group and 30 in control group). Subjects were selected using purposive sampling technique. **Intervention:** Children in the experimental group were administered oral glucose (25% dextrose) of 1 ml was administered with dropper 2 seconds prior to the invasive procedure. . Nothing was given for the children in control group. **Main outcome measure:** investigator assessed the level of pain with CRIES pain scale (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness). **Findings**: The overall mean score of experimental and control group during invasive procedures. The control group mean (7.63) is higher than the experimental group mean (4.26) of the infants. The obtained 't' value is 15.9, significant at $p<0.005$ level.

This shows that experimental group experienced less pain than control group. Hence, administration of oral glucose had effect on reducing the pain during invasive procedures. **Conclusion:** The study concluded that oral glucose had effect on reducing the pain for infants during invasive procedures. This non-pharmacological pain reducing technique is highly recommended because it is effective, easy to carry out.

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CHAPTER I

INTRODUCTION

"It's so hard to forget pain, but it's even harder to remember sweetness. We have no scar to show for happiness. We learn so little from peace."

— Chuck Palahniuk,

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. The experience of pain is always subjective. Hence, verbalization of nociceptive sensation is the gold standard for assessment of pain. Since infants cannot verbalize their pain, the recognition and management of pain in infants is still suboptimal. Studies have documented that babies born at less than 32 weeks of gestation are exposed to 10–15 painful procedures each day during the first few weeks of life, and in almost 80% no treatment for pain relief is offered. Pain in infants is known to cause adverse short and long-term effects. A host of physiological, biochemical and behavioral responses have been noted during painful episodes. When exposed to prolonged pain, infants enter a state of passivity with few, if any, body movements; they have an expressionless face, decreased heart rate and respiratory variability, and decreased oxygen consumption, all suggestive of a marked conservation of energy. Prolonged or repeated pain also increases the response elicited by future painful stimuli (hyperalgesia) and even by usually non-painful stimuli (allodynia).

The myth regarding infant pain suggests that because of neurological immaturity, infants does not experience pain. However, studies have shown that the pain pathways as well as cortical and sub-cortical centers, necessary for pain perception are well developed late in gestation, and physiological and behavioral

response to pain are well documented in infants. The response to pain in infants consists of behavioral, psychological, and social changes. The cognitive ability, trust of care givers and previous painful experiences will influence this response.

Infants routinely experience pain associated with invasive proceduress such as blood sampling, Injections, vitamin K injection or circumcision. The sick or preterm infant may experience repetitive or prolonged pain resulting from many diagnostic, surgical or therapeutic procedures. Although the exact gestational age of nociceptive capacity to feel pain has not readily been determined, the fetus is likely to have the nociceptive capability to feel pain from around 20-24 weeks of gestational age. There is now a growing body of evidence that multiple painful and stressful events undergone by infants born prematurely not only induce acute changes, but that permanent structural and functional changes may also result. Therefore a proper management analgesia in newborns who require medical procedures is mandatory. Oral sucrose, with and without nonnutritive sucking, has been the most frequently studied non pharmacological intervention for pain relief during minor procedures in infants.

Oral glucose was effective in reducing symptoms associated with pain from venipuncture in term infants7-8 but the analgesic effects of oral glucose in premature infants has not yet been reported in literature. The aim of this study is to prove the effectiveness of orally administered glucose during invasive proceduress in infants.

In a series of studies, oral sucrose or glucose has been used to alleviate pain reactions during blood sampling, by heel stick or venupuncture. Other interventions such as non-nutritive sucking skin-to-skin contact and swaddling have also been proposed as means of reducing pain during blood sampling in newborns. Throughout

history, feeding has been used to calm and comfort infants. Today, many care professionals encourage breast-feeding before a painful procedure to keep the neonate satisfied and not showing so much pain. There are few scientific studies in this field. Gray and colleagues found that among infants undergoing blood sampling, those who were breast-fed during the procedure showed less crying and grimacing than control infants. Bilgen et al. reported that breastfeeding during blood sampling was less effective than oral sucrose, on the basis of the crying time and behavioral variables, and Carbajal et al. found breast-feeding superior to water or holding but noted no difference between the effects of breast-feeding during blood sampling and orally given glucose.

Time since feeding is often stated among background characteristics in studies about neonatal pain, indicating this to be important for the response to a painful procedure. Whether the time since feeding correlates with pain response is rarely studied. In a study on pain response at 4- or 6-month vaccination, Taddio et al. found that time of last feeding did not correlate significantly with pain response. Studies looking at pain response in newborns recently fed versus not fed has so far not been performed. As pain is a multidimensional phenomenon, a multidimensional measure of pain, combining behavioral and physiological factors with contextual factors such as gestational age and behavioral state, has been found to be superior to other measures.

The use of oral sucrose has been the most extensively studied pain intervention in newborn care to date. More than 150 published studies relating to sweet-taste-induced calming and analgesia in human infants have been identified, of which 100 (65%) include sucrose. With only a few exceptions, sucrose, glucose, or

other sweet solutions reduced pain responses during commonly performed painful procedures in diverse populations of infants up to 12 months of age. Sucrose has been widely recommended for routine use during painful procedures in newborn and young infants, yet these recommendations have not been translated into consistent use in clinical practice. One reason may be related to important knowledge and research gaps concerning analgesic effects of sucrose. Notably, the mechanism of sweet-taste-induced analgesia is still not precisely understood, which has implications for using research evidence in practice.

Any invasive proceduress in outpatient department nursery care are common even that causes pain to the infant. Recent studies have proven that, the babies early pain experience may alter their pain response in later life. Many attempts have been made to reduce the pain sensation in infants undergoing invasive proceduress. One of the most studied methods are administration of sucrose or dextrose, before the heel prick, which has been shown effectively reduce pain sensation in infants.

When a baby is born, an orderly continuous adaption from fetal life to extra uterine life takes place. The body system undergoes some changes during that time. The most profound physiologic change required of the new born is the transition from fetal or placental circulation to independent respiration.Neonates are unique in their physiology and the health problems that they experience

1.1 NEED FOR STUDY:

Injections are the most aversive medical procedures for healthy infants and children and are the most common source of childhood iatrogenic pain. The unpleasant sensory and emotional responses that result from the pain of Injections may induce the fear of needle sticks for these children. Painful procedures are likely to be confounded with anticipatory and concurrent anxiety, usually considered together as procedure related distress. Studies based on 2005 census, revealed that Injections program could cover about 100% of target children in India.

The effect of oral administration of sweet solutions has been often investigated and proved to be an effective alternative. The effect of sweet solutions on pain cannot be fully explained but activation of the endogenous opiates is often described as a potentially responsible process. The sweet solution puts two mechanisms into action; first, a tactile stimulation of fluid in the mouth provides and initiates effect and second, the sense of taste stimulation prolongs the effect through the release of endogenous opiates. Stimulation of the taste buds is needed to obtain the analgesic effect, as administration directly in to the stomach appears to be ineffective. Sucrose and glucose are the most common sweet solutions, and are effective, easy to use and safe.

Adequate management of pain in infants has been handicapped by a number of factors. Infants were often treated as though they did not experience pain while undergoing invasive proceduress. In 1986, paper on attitude towards pain in children revealed that 40% subjects who were paediatricians, surgeons and family practitioners suggested that infants do not experience pain in their first month of life. It was common before the 1990's for new born to undergo surgery with minimal anesthesia

and did not receive essential post operative pain management. They were also subjected to painful procedures such as lumbar puncture, circumcision and ABG sampling without consideration of their discomfort or potential negative long term consequences.

The thoughtful work of Anand et al and Fitzgerald et al who defined pain transmission in neonates and identified negative consequences due to inadequate treatment of pain manifested a dramatic impact on changing practices towards pain relief in new born period. More recently Mc Laughlin et al found that 99% of nurses who work with newborns believe that they do experience pain. Parents are likely to have a substantial impact on child's experience of pain. Studies reported that parents of children who have functional disability related to chronic pain problems more often discouraged their child's adaptive coping behaviors and reward their child's pain behavior, in comparison to parents whose children with chronic pain had low levels of functional disability.

Approaches to preparing a child for a needle procedure obviously vary according to the age of the child. This involves primarily preparing the parents who had infants. Whereas for toddlers and older children this has to be discussed with the child itself. Several pharmacological and physical approaches have been developed in an attempt to reduce pain at the injection site.

Cognitive and behavioral techniques such as parental presence reduce the anxiety associated with injections. Distraction techniques such as hypnosis, use of bubble solutions, party blowers and pin wheelers have dramatically reduced sharp pain. Other strategies for pain reduction include use of favourite stories, kaleidoscopes, listening to music and other type of meditations.

In infants administration of 25% oral glucose solution placed in pacifier or on the tongue has dramatically reduced the pain while doing invasive proceduress. Barr et al and others have shown that this effect gradually decreases over time and is most potent in first few months of life and essentially gone by six months. Other investigators have shown that the effect of sucrose is not only one of the distracters but may be mediated through opioid pathways. The sucrose will block the pain fibres running down through the spinal cord which may occur during sucking which in turn have an analgesic effect. Encountering pain is one of the common paediatric practices. Having worked in the Injections clinic, the investigator came across many infants who were screaming due to pain during Injections. This caused psychological impact for parents and difficulties in administering Injections by the health workers. This inspired the investigator to look out for an alternate method which would reduce the pain threshold of infant during Injections.

The CRIES pain scale (Cry, Requirement of oxygen, Increase in vital signs, Expression, Sleeplessness) fulfils this requirement and is easy to use for research about effectiveness of pain-relieving methods, and in clinical practice, it would also be easier if the parents could assess the infants' pain by themselves. Prolific research concerning pain reducing properties of sucrose has been conducted over the past 25 years, with indisputable evidence that small volumes significantly reduce behavioral responses and composite pain scores to painful procedures in newborn and young infants. Recommendations for practice include using small volumes of sucrose for painful procedures only; avoiding use for calming irritable infants who are not undergoing procedures; giving solutions in aliquots over the duration of the procedure for prolonged procedures; avoiding use of 10 doses per 24 hours, especially during the first week of life; and using other effective strategies during painful procedures when

feasible. Future research needs to address remaining areas of uncertainty with the ultimate aim of ensuring that no infant suffers unnecessary pain during painful procedures.

1.2 STATEMENT OF THE PROBLEM:

"A study to assess the effectiveness of oral glucose on pain response among infants during invasive procedures, paediatric outpatient department, Government Rajaji Hospital, Madurai"

1.3 OBJECTIVES:

- To assess the pain response of infants during invasive proceduress for both the control group and experimental group.
- To compare the pain response during invasive proceduress of infants between control group and experimental group.
- To determine the association between pain response and the selected baseline variables among infants in experimental group.

1.4 HYPOTHESES

H_1- There will be significant difference in pain response among infants in control group and experimental group.

H_2- There will be significant association between pain response and the selected baseline variables among infants in experimental group.

1.5 OPERATIONAL DEFINITION:

EFFECTIVENESS **:** In this study effectiveness refers to determining the extent to which the oral glucose solution has decreased the pain response as evidenced by scores on CRIES pain assessment scale for infants.

ORAL GLUCOSE **:** In this study oral glucose refers to administration of 25% Dextrose orally of 1 ml by using dropper during invasive procedures.

PAIN **:** In this study pain refers the discomfort arising from the invasive procedures, which is measured with the help of CRIES pain scale (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness)

INFANTS **:** Children within the age group of 0 -1 year.

INVASIVE PROCEDURESS : In this study invasive proceduress includes IM injection and collection of blood sample.

ASSUMPTIONS:

1. Invasive proceduress are common for infants in paediatric outpatient department.
2. Invasive proceduress evoke pain response in infants.

1.6 DELIMITATIONS:

1. The study is limited only to infants.
2. The study is limited only to the period of six weeks.

1.7 PROJECTED OUTCOME:

This study will reveal that pain response experienced by the infants during invasive procedures at paediatric outpatient department, Government Rajaji Hospital, Madurai. It will give strong evidence that the infants who receive oral glucose will experience reduced levels of pain compared to the infants who are not receiving anything during invasive procedures. In addition, the results will motivate the health care workers to use this non pharmacological and cost effective technique to reduce the pain during invasive proceduress.

CHAPTER – II

REVIEW OF LITERATURE

A literature review is a body of text that aims to review the critical points of knowledge on a particular topic of research. (American Nurses Association, 2000). The literature review is used in two ways by the research community. The first refer to the activities involved in identifying and searching for information on a topic and the second one is developing an understanding of the state of knowledge on the topic.

This chapter deals with two parts:

Section A : Review of literature

Section B : Conceptual framework on modified general system theory by Ludwig Von Bertanffy.

SECTION - A

The literature has been organized under following sections:

In this study the review of literature is classified into two sections.

1. Studies related to infant pain and assessment.
2. Studies related to strategies to reduce pain during invasive proceduress.
3. Studies related to effect of oral analgesia to reduce pain among infants.

1. Studies related to infant pain and assessment.

Andersen RD et.al (2013) conducted a study on Cultural adaptation of patient and observational outcome measures: A methodological example using the COMFORT behavioral rating scale.This study explores the use of cognitive interviews in the translation and cultural adaptation of observational measures, using the COMFORT behavioral scale as an example, and demonstrates a structured approach to the analysis of data from cognitive interviews. The COMFORT behavioral scale is developed for assessment of distress and pain in a pediatric intensive care setting. Qualitative, descriptive methodological study. We translated the COMFORT behavior scale into Norwegian before conducting individual cognitive interviews. Participants first read and then used the translated version of the COMFORT behavioral scale to assess pain based on a 3-min film vignette depicting an infant in pain/distress. The author concluded that Cognitive interviews revealed problems with both the translated and the original versions of the scale and suggested solutions that enhanced the validity of both versions. Cognitive interviews might be seen as a complement to current published best practices for translation and cultural adaptation.

Deindl P et.al (2013) conducted a study on Successful implementation of a neonatal pain and sedation protocol at 2 NICUs. The objective is to evaluate the implementation of a neonatal pain and sedation protocol at 2 ICUs. The intervention started with the evaluation of local practice, problems, and staff satisfaction. We then developed and implemented the Vienna Protocol for Neonatal Pain and Sedation. The protocol included well-defined strategies for both nonpharmacologic and pharmacologic interventions based on regular assessment of a translated version of the Neonatal Pain Agitation and Sedation Scale and titration of analgesic and sedative therapy according to aim scores. Health care staff was trained in the assessment by using a video-based tutorial and bedside teaching. In addition, we performed reevaluation, retraining, and random quality checks. Time on mechanical ventilation, length of stay at the ICU, and adverse outcomes were similar before and after implementation. The researcher concluded that Implementation of a neonatal pain and sedation protocol at 2 ICUs resulted in an increase in opiate prescription, pharmacologic interventions, and staff satisfaction without affecting time on mechanical ventilation, length of intensive care stay, and adverse outcomes.

Weiser G, et.al (2013) Premedication with midazolam for urethral catheterization of febrile infants.Febrile infants undergoing urethral catheterization (UC) are often not treated for pain and distress. The aim was to evaluate the effectiveness of midazolam premedication. We compared a convenience sample of infants who underwent UC with midazolam with those who did not receive midazolam. Outcome measures were Visual Analog Scale assessment, duration of cry, and emergency department length of stay. Thirty-two study participants and 18 controls were prospectively enrolled. Midazolam premedication showed a 53% decrease in the mean Visual Analog Scale score when parents assessed distress and a

48% decrease when nurses assessed distress the median cry duration was significantly shorter. Serious adverse events were not observed during sedation and at 48 h after discharge. Study participants had longer emergency department length of stay compared with the controls. In this cohort, midazolam significantly reduced the distress associated with UC without causing serious adverse events.

Lucas C et.al (2012) does postoperative 'M' technique massage with or without mandarin oil reduce infants' distress after major craniofacial surgery. The aim of the study is a report of a randomized controlled trial of the effects of 'M' technique massage with or without mandarin oil compared to standard postoperative care on infants' levels of pain and distress, heart rate and mean arterial pressure after major craniofacial surgery. There is a growing interest in non-pharmacological interventions such as aromatherapy massage in hospitalized children to relieve pain and distress but well performed studies are lacking. This randomized controlled trial allocated 60 children aged 3-36 months after craniofacial surgery from January 2008 to August 2009 to one of three conditions; 'M' technique massage with carrier oil, 'M' technique massage with mandarin oil or standard postoperative care. Primary outcome measures were changes in COMFORT behaviour scores, Numeric Rating Scale pain and Numeric Rating Scale distress scores assessed from videotape by an observer blinded for the condition. In all three groups, the mean postintervention COMFORT behaviour scores were higher than the baseline scores, but differences were not statistically significant. Heart rate and mean arterial pressure showed a statistically significant change across the three assessment periods in all three groups. These changes were not related with the intervention. The author concluded that results do not support a benefit of 'M' technique massage with or without mandarin oil in these young postoperative patients. Several reasons may account for this: massage given too

soon after general anaesthesia, young patients' fear of strangers touching them, patients not used to massage.

Ottenhoff MJ, et.al (2012) conducted a study on Discomfort and pain in newborns with myelomeningocele: a prospective evaluation. The objective of the study in In a worldwide debate on deliberately terminating the lives of newborns, proponents point at newborns with very severe forms of myelomeningocele (MMC) and their assumed suffering, claiming there are no effective means of alleviating their distress. The primary outcomes were discomfort and pain, assessed by simultaneously scoring 2 validated scales: the visual analog scale for pain and the Comfort Behavioral Scale for discomfort. These scores were coupled to a validated and evidence-based analgesia algorithm. Overall, discomfort related to pain was measured in 3.3% of the scores. The researcher concluded that Over the length of their hospital stays for initial treatment, all newborns with MMC presented with low levels of discomfort and pain independent of disease severity and time frame.

Oberlander TF et.al (2010) conducted a study on Prenatal alcohol exposure alters biobehavioral reactivity to pain in newborns. The objective is to examine biobehavioral responses to an acute pain event in a Cape Town, South Africa, After a feeding and nap, newborns were administered an abbreviated Brazelton Neonatal Behavioral Assessment Scale. There were no between-group differences in maternal age, marital status, parity, gravidity, depression, anxiety, pregnancy smoking, maternal education, or infant gestational age at birth. In both groups, HR increased with the heel lance and decreased during the postlance period. The researcher concluded that to our knowledge, these data provide the first biobehavioral examination of early pain reactivity in alcohol-exposed newborns and have important

implications for understanding neuro-/biobehavioral effects of prenatal alcohol exposure in the newborn period.

Keefe MR et.al (2008) conducted a study on Newborn predictors of infant irritability. The objective of the study is to identify newborn infant behaviors that may predict infant irritability, commonly referred to as colic. A prospective, correlational design, with data collection occurring the first 4 days of life and again at 1 month of age. This study was conducted in a private hospital in a large metropolitan city in the Midwest. At 1 month of age, irritability was measured using the Fussiness Rating Scale. These were the cluster of variables representing motor activity and the Neonatal Behavioral Assessment Scale supplemental item measuring the persistence necessary on the part of the examiner to get the infant to attend to stimuli presented. The infants who were classified by parents as irritable at 1 month of age were more active and more attentive to stimuli in the first few days of life. The researcher concluded that the newborn nursery nurses cry ratings were not related to the later development of colic in these infants. Active infants who are sensitive to stimuli may be predisposed to infant irritability; however, further work is needed to understand the relationships of these infant characteristics to the human interactions and physical environments they encounter.

Hatfield LA.et.al (2008) conducted a study on Sucrose decreases infant biobehavioral pain response to immunizations: a randomized controlled trial. The purpose of the study is to evaluate the effectiveness and age-related changes in analgesia of oral sucrose as a preprocedural intervention during routine immunizations in infants at 2 and 4 months of age.A double-blind, randomized, placebo-controlled clinical trial of 40 healthy term infants scheduled to receive routine immunizations from a pediatric ambulatory care clinic during May 2005 to

July 2005.Infants received 24% oral sucrose solution or the control solution of sterile water 2 minutes before routine immunizations at both their 2- and 4-month, well-child visits. The University of Wisconsin Children's Hospital pain scale was used to measure serial acute behavioral pain responses at baseline, 2, and 5 minutes after administration of the solution. Repeated measures ANOVA was used to examine between-group differences and within-subject variability of the effects of treatment on overall behavioral pain scores. The researcher concluded that Sucrose is an effective preprocedural intervention for decreasing behavioral pain response in infants after immunizations.

Reinthal M, et.al (2008) conducted a study on Effects of minimal acupuncture in children with infantile colic - a prospective, quasi-randomised single blind controlled trial. Colic causes crying in 10-30% of infants and is one of the primary reasons parents seek health care. Treatments are generally not totally effective and some cause side effects. In this study we aimed to test the effect of light needling (minimal acupuncture) on crying. Parental assessment questionnaires were used pre- and post-treatment to assess crying intensity, frequency, duration of crying and pain related behaviour throughout the day in six hour periods. Light needling resulted in a significant reduction in the rated crying intensity (assessed by a numeric rating scale, 0 to 10). Pain related behaviour like facial expression, was also significantly less pronounced in the light needling group as compared to the control group post-treatment, (P=0.027). The parents rated the light needling as more effective in improving symptoms than the control group (P<0.001). the researcher concluded that Four treatments with light needling on one point in the hand may alleviate crying and pain related behaviour without any noted side effects.

2. Studies related to strategies for reducing pain during invasive proceduress.

Gibbin S et.al (2012) conducted a study to compare acute pain response during immunization in infants using a slow standard technique versus a rapid pragmatic technique by randomized controlled trial. One hundred and thirteen infants participated. In standard group slow aspiration prior to injection, slow injection and slow withdrawal technique was used. Whereas in pragmatic group no aspiration, rapid injection and rapid withdrawal technique was used. Infant's pain was measured by modified behavior pain scale. The findings indicated that mean modified behavioural pain scores were higher in standard group i.e., 5.6 when compared to pragmatic group i.e., 3.3 and there were no observed difference in age, birth order or prior analgesic use.

Bamswebber et.al (2012) A study was conducted on heel lance in newborn during breastfeeding. The aim of study was to evaluate the analgesic effect of breastfeeding during heel puncture in full term health infant. Out of 200 healthy full term newborns (100 cases and 100 controls), the puncture was proposed to infants during breastfeeding, and the mothers were explained the advantages of this practice. Pain was assessed by using DAN scale (Douleur Aigue Nouveau ne scale). The result of the study showed that the difference in the score pain according to the DAN scale was significant in the two groups of patients (p=0.000); the medium score was 5.15 for controls and 2.65 for cases (newborns sampled during breastfeeding). This study confirmed the evidence of analgesic effect of breastfeeding during heel puncture.

Jahab Rao et.al (2012) conducted a comparative study among children less than 24 months to assess the efficacy of Eutectic mixture of local anesthetics with pre mixed 50% nitrous oxide/ oxygen, used alone or combined with eutectic mixture for pain alleviation during immunization with palivizumab injection. Randomized double

blind technique was used. Three different analgesic interventions were used. Eutectic mixture of local anesthetics application plus air inhalation. Inhalation of 50:50 nitrous oxide and oxygen mixture plus application of placebo cream. Nitrous oxide: oxygen inhalation plus eutectic mixture of local anaesthetic application. The results revealed that the combined nitrous oxide/ oxygen plus eutectic mixture of local anaesthetics was more effective than either local anesthetics or nitrous oxide or oxygen.

Rahm VA et.al (2011) conducted a comparative study to assess the effectiveness of kangaroo care and giving prone position on physiologic responses during IM injections in infants was done and 100 infants were randomly assigned to both intervention and control groups. In the intervention group, the neonate was held in kangaroo care for 10 minutes before injection until three minutes after injection and in the control group the neonate was in the prone position isolated without caregiver. The primary outcomes were measured by heart rate and blood oxygen saturation rate before, during and three minutes after injection. The findings revealed that the heart rate during and three minutes after injection for infants of intervention group was significantly lower than the infants in control group[21]. However the heart rate and oxygen saturation were found to be normal for both groups.

Thyr M et.al (2010) conducted a study on 66 infants with 33 on the experimental and 33 on the control group regarding the strategies to reduce pain by using parental support. The findings revealed that, excessive parental apology increased the distress, whereas humour and distraction may reduce the distress. The age, interest of the child as well as personal style of the parents determined the effective distraction technique. These techniques may include story telling, reading to the child and holding the child.

Stevenson et.al (2010) conducted a study to compare the effectiveness of needle free jet injection by intra dermal route compared with intra muscular injection with 0.25ml of influenza vaccine by needle syringe on 6 to 24 months old children, by using controlled double blind technique. The findings revealed that intra dermal needle free jet injection in 6 to 24 months old children was found to be more effective in pain reduction when compared to the IM injection. The calculated pain score is found to be on an average of 4 as compared to 6 to 8 for control group which was measured by visual analogue scale.

2. Studies related to the effect of Oral analgesia to reduce pain among infants.

Pandy M et.al (2012) conducted a study on the efficacy of repeated versus single dose sucrose**,** to reduce pain from routine heel stick procedure in pre term infants. Infants (n=48) in the first week of life with mean gestational age of 31 weeks received 0.05ml of 24% sucrose solution or sterile water orally thrice, i.e., (1) 2 min prior to actual lancing of the heel; (2) Just prior to lancing, and (3) 2 min after lancing. The single dose group received sucrose for the first dose and water for the second and third dose; the repeated dose group received sucrose 3 times and placebo group received only water. Pain was measured by Premature Infant Pain Profile (PIPP) scores for five times on a 30 second interval after lancing. Infants with sucrose orally have lower PIPP scores when compared to infants with water and infants in the repeated dose had lower scores than infants with single dose.

Beune et.al (2012) conducted on expressed breast milk versus 25% dextrose in procedural pain in infants. A double blinded randomized control trial. The objective of the study was to compare the effect of expressed breastmilk (EBM), 25% dextrose (25 D) and sterile water (SW) on procedural pain in neonates as assessed by

the premature infant pain profile (PIPP), changes in heart rate, oxygen saturation, and duration of crying. Among 210 babies who required venipuncture for blood sampling and who were recruited for the study after obtaining parenteral informed consent in a postnatal ward of a tertiary care hospital. One ml of test solution was given to baby by palade 2 min prior to venipuncture. The face and crying of babies were video graphed by an independent blind observer. 160 babies were considered for final analysis with 50 in 25D. the study concluded that EBM significantly reduced procedural pain in infants through to a lesser extent when compared to 25% dextrose.

Nimbalkar S et.al(2012) conducted a study in Reduction of Neonatal Pain Following Administration of 25% Lingual Dextrose: A Randomized Control Trial.Infants experience painful procedures during routine care. Orally administered, sweet tasting solutions are commonly used in management of neonatal pain. We conducted a double-blind randomized control trial in infants admitted to Neonatal Intensive Care Unit of Shri Krishna Hospital, Karamsad-Gujarat-India, of lingual administration of 25% dextrose vs. no intervention, to evaluate reduction of pain following oropharyngeal infantfeeding tube insertions. Pain was assessed using Premature Infant Pain Profile score. Almost all the patients in the control group (98%) experienced moderate-to-severe pain as compared with the intervention group (71%). Mean Premature Infant Pain Profile score was statistically significantly lower in the intervention group (8.21) as compared with control group (10.31). ($p < 0.001$, 95% CI 1.090-3.102). Lingual 25% dextrose is an effective analgesic for relieving pain during orogastric tube insertion.

Datta et.al (2011) conducted a study on the effectiveness of sucrose analgesia in new born undergoing painful medical procedure by using a double blind

randomized controlled trial in new borns greater than 36 weeks of gestation of diabetic and non diabetic mothers. Each new born received 2 ml of a 24% sucrose or placebo solution before all procedures. Premature infant pain profile scale was used for assessment of pain. The overall mean pain score was lower among new borns who received sucrose than among those who received a placebo. The pain scores during IM injection did not differ significantly between the sucrose and placebo groups for new borns of diabetic or non diabetic mothers. During venipuncture, new borns who received sucrose had lower pain scores compared to those who received a placebo.

Rahey et.al (2011) conducted a comparative study was conducted in two Swedish hospitals among 201 infants with gestational age of 36 weeks or more and a postnatal age less than 30 days to assess pain reducing effect of orally administered glucose with that of Eutectic mixture of local anaesthetic (EMLA) cream during venipuncture by using controlled randomised, and double blind trial. Ninety nine infants of control group were given EMLA on the skin and orally administered placebo, and 102 infants of experimental group received 30% glucose orally and placebo on the skin. Symptoms associated with pain at venipuncture were measured with the Premature Infant Pain Profile scale. The result revealed that the Premature Infant Pain Profile scores were significantly lower in the glucose group than in the EMLA group.

Hasehel et.al (2010) conducted a Turkish study was carried out to identify the pain relieving effect of breast feeding during immunization through needle prick in healthy infants. Sixty six healthy infants returning to a clinic for their second, third or fourth month immunization with intramuscular route for diphtheria, tetanus, and pertusis were randomized to be breast fed before, during and after the injection. The

control group was not breast fed before, during or after the immunization. The pain responses of the infants during and after immunization were assessed by observing, the heart rates, oxygen saturation levels, and length of cry of the infants. The crying time was shorter in the experimental group than in the control group. The heart rate and oxygen saturation levels were almost same in both groups.

Dilen B et.al (2010) conducted a study to assess Oral glucose solution as pain relief in newborns: results of a clinical trial. It was long believed that newborns could not experience pain. As it is now documented that newborns have all the necessary systems to perceive pain, pain management can no longer be ignored. The objective of this study is to investigate which concentration of glucose is most effective in reducing pain for venipuncture in the newborn. This double-blind clinical trial of 304 newborns was conducted on a maternity and neonatal ward (neonatal medium intensive care unit). During at least 1 month, one of the four selected solutions (10, 20, 30% glucose, and placebo) was administered orally, 2 minutes before the venipuncture was performed. The pain from the skin puncture was scored using a validated pain scale (the "Leuven Pain Scale"). This study showed a significantly lower average pain score in the 30 percent glucose group (3.99) when compared with the placebo group (8.43). The average pain scores in the 20 percent glucose group (5.26) and the 10 percent glucose group (5.92) were also significantly lower than those in the placebo group. Oral administration of 2 mL of 30 percent glucose 2 minutes before the venipuncture provides the most effective pain reduction in newborns.

Harrison D et.al (2010) conducted a study to assess the Efficacy of sweet solutions for analgesia in infants between 1 and 12 months of age: a systematic

review. To compare the efficacy of oral sweet solutions to water or no treatment in infants aged 1-12 months during immunisation.Randomised controlled trials (RCTs) were retrieved through internet searches or manual searches of reference lists. Search terms included newborn, infant, pain, sucrose and alternative names for sweet solutions. Summary estimates with 95% CIs were calculated and included relative risk (RR), risk difference (RD) and number needed to treat to benefit (NNTB) for dichotomous outcomes, and weighted mean differences (WMD) for continuous outcomes. Where pooling of results was not possible, a narrative summary of study results is presented. Of the 695 studies identified, 14 RCTs with 1674 injections met the inclusion criteria. Sucrose or glucose, compared to water or no treatment decreased crying during or following immunisation in 13 of the 14 studies. Infants receiving 30% glucose (three trials, 243 infants) had a decreased RR in crying incidence following immunisation (typical RR 0.80, 95% CI 0.69 to 0.93; RD -0.17, 95% CI -0.29 to -0.05; NNTB 6, 95% CI 3 to 20). With sucrose or glucose, there was a 10% WMD reduction in proportion of crying time (95% CI -18 to -2) and a 12 s reduction in crying duration (95% CI -23 to -0.7 s). An optimal dose of sucrose or glucose could not be ascertained due to the varied volumes and concentrations used. Infants aged 1-12 months administered sucrose or glucose before immunisation had moderately reduced incidence and duration of crying. Healthcare professionals should consider using sucrose or glucose before and during immunisation.

Stevenson et. Al (2004) conducted a study to compare the efficacy of oral sweet solutions to water or no treatment in infants aged 1–12 months during immunisation. Randomized controlled trials (RCTs) were retrieved through internet searches or manual searches of reference lists. Search terms included newborn, infant, pain, sucrose and alternative names for sweet solutions. Summary estimates with 95%

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Yamada et.al (2003) a conducted a study to assess the effect of breastfeeding, oral sucrose and combination of oral sucrose and breastfeeding in infant's pain relief during the vaccination Pain is a global health problem which exists from the birth to the last stage of the life. It has been proven that infants are able to feel the painful stimulus. Infants routinely experience the pain in the hospitals especially during the vaccination procedure. Therefore, finding out a non pharmacological method is necessary for pain relieving. The aim of this study was to compare the effect of oral sucrose, breastfeeding and combination of them on pain relief vaccination of less than 3 months of age infants with the first time vaccination in Tabriz.In this quasi-

experimental study, 120 under 3 months of age infants referred to Tabriz Health Centers in 2009. The eligible infants referred to the centers entered the study provided with entry criteria. They referred to the mentioned centers then entered the study and finally randomly have been put into four groups respectively; oral sucrose 25%, breastfeeding, combined method and control groups.

CONCEPTUAL FRAMEWORK:

Conceptual framework is a set of global ideas about the concepts in relation to a specific discipline. A conceptual framework is the network of inter related concepts that provide a structure for organizing and describing the phenomenon of interests.

A concept is a thought, ideas or mental image framed in the mind in response to learn something new. A framework is a basic structure supporting anything, it guides an investigator to know what data needs to be collected and gives the right direction to the research process.

The conceptual framework of the present study is based on modified Ludwig Von Bertalanffy (1980). This theory is used as a universal theory that could be applied to many fields of study. Nurses are increasingly using system theory to understand the biological system and systems in families, communities, nursing and health care. A system is a group of interrelated exclusive components and it is based on the eminence and extent of the input, throughput, output and feedback.

Input

Based on Ludwig Von Bertalanffy, Input consists of information, matter or force that enters the system. In this research study, the behavioural and physiological responses of pain were assessed by using modified CRIES pain scale as input.

Throughput

After immersing the input it is processed in a way that is beneficial for the system. This information is known as throughput. In this subjects were grouped into experimental and control group. Oral glucose (25% dextrose) of 1ml was administered 2 seconds prior to invasive procedures with the help of dropper. Nil intervention was given to subjects in control group. After intervention, pain was assessed with the help of CRIES pain assessment scale which act as throughput of the study.

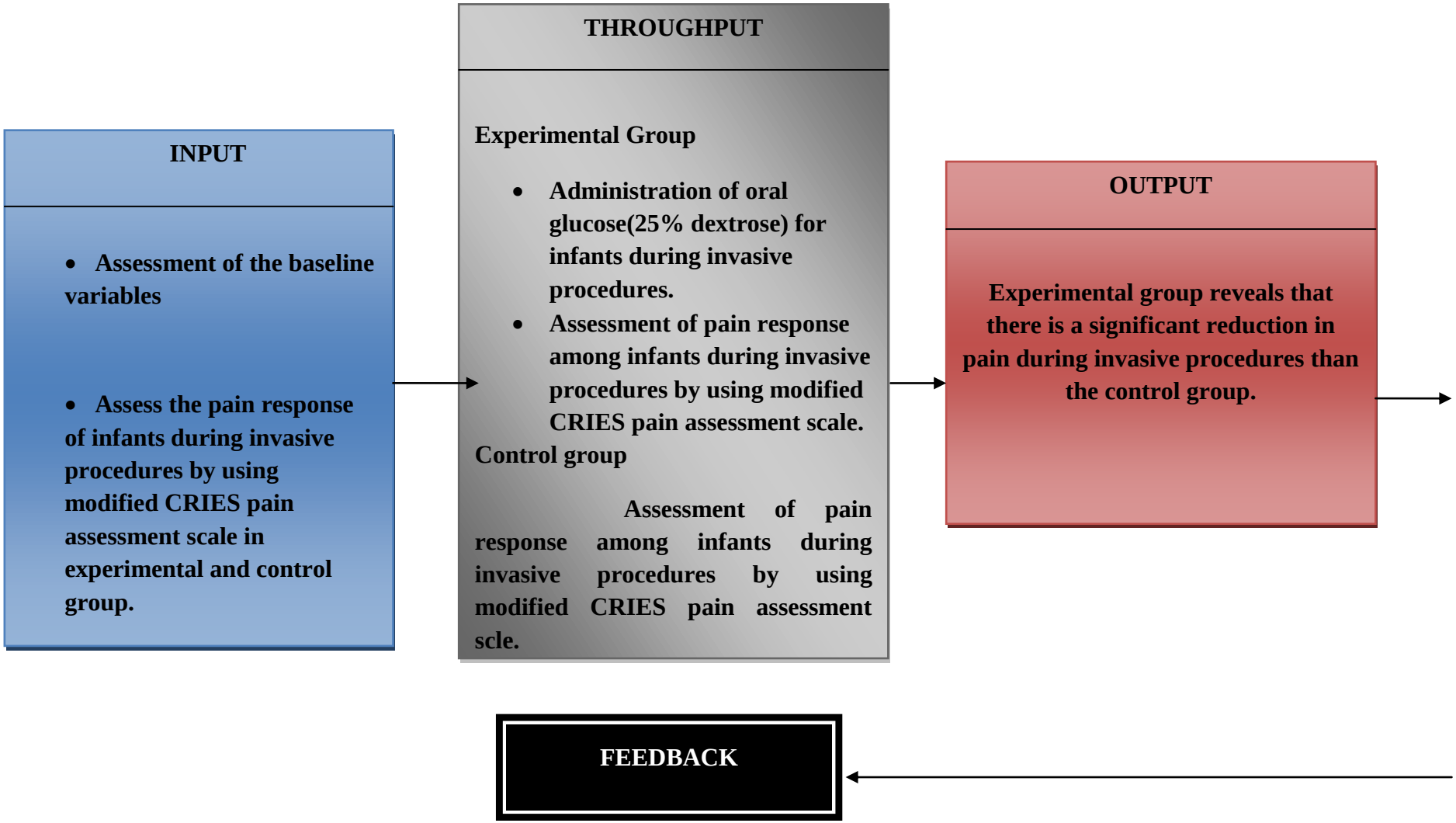
Output

Output from a system is force, stuff or information given out by the system as a result of its processes. The reduction in the pain of infants during invasive proceduress after administration of oral glucose act as an output of the study.

Feedback

Feedback enables a system to regulate itself by redirecting the output of a system into the system as input, thus forming a feedback. The results reveals that there is a significant reduction in the pain of infants during invasive procedures after administration of oral glucose to experimental group, which act as the feedback for the nurse to administer oral glucose prior to invasive procedures.

FIG 1: CONCEPTUAL FRAMEWORK ON MODIFIED GENERAL SYSTEM THEORY BY LUDWIG VON BERTANFFY (1968)



CHAPTER - III

METHODOLOGY

This chapter includes research approach, research design, variables, setting, population, sample and sample size, sampling technique, development of the tool, content validity, pilot study, data collection procedure, plan for data analysis, and ethical consideration.

3.1 RESEARCH APPROACH

Quantitative approach was used for the study to evaluate the effectiveness of oral glucose on pain during invasive procedures in paediatric outpatient department, Institute of Child Health and Research Centre, GRH, Madurai.

3.2 RESEARCH DESIGN

The research design selected for the present study was Quasi Experimental Study. A Quasi experimental involves Manipulation and Control. The study was intended to evaluate the effectiveness of oral glucose technique on pain during invasive procedures among the infants of paediatric outpatient department, Institute of child health and research centre, GRH, Madurai.

GROUP	INTERVENTION	POST TEST
Experimental group	X	O1
Control group	-	O1

O1 - Post test for both experimental group and control group

X - Intervention to experimental group (Administration 25% oral glucose orally)

3.3 VARIABLES

Variables included in the study were

- **DEPENDANT VARIABLE:** Pain response
- **INDEPENDENT VARIABLE:** Oral glucose
- **DEMOGRAPHIC VARIABLE:** Age, sex, term, weight of baby, type of delivery, type of family, place of residence, mothers literacy level, birth order, and type of feeding.

SETTING OF THE STUDY

The study was conducted at paediatric outpatient department, Institute of Child Health and Research Centre, Government Rajaji Hospital, at Madurai. Monthly more than 250 infants were receiving invasive proceduress.

POPULATION

TARGET POPULATION:

Infants undergoing invasive procedures.

ACCESSIBLE POPULATION:

Infants undergoing invasive procedures at paediatric outpatient department, Institute of Child Health & Research centre, GRH, Madurai.

SAMPLE SIZE

The total sample - 60; Experimental group – 30, Control group – 30.

SAMPLING CRITERIA

The following were the criteria for selection of samples for the study.

INCLUSION CRITERIA:

1. Infants within age group 0-1 year.
2. The infants who underwent invasive procedures.
3. The mothers of the infants who were willing to participate in the study.

EXCLUSION CRITERIA:

1. The infants who were admitted in paediatric ward.
2. The infants with congenital anomalies. Eg. Cleft Lip, Cleft Plate.
3. The infants who were under emergency care.

3.8 SAMPLING TECHNIQUE

Purposive sampling technique was adopted in this study.

3.9 RESEARCH TOOL

The tool was developed after extensive review of literature, internet sources and discussion with experts. The tool consists of following two sections;

SECTION I : Baseline variables.

SECTION II : Modified CRIES pain scale (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness)

3.9.1 DESCRIPTION OF THE TOOL

Section I: It consists of 10 items seeking information about Age, sex, term, birth weight, type of delivery, type of family, place of residence, mothers literacy level, birth order, and type of feeding.

Section II: Modified CRIES pain scale: (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness). The CRIES scale was developed by

Sandra Merkel, MS, RN, Terri Voepel-Lewis, MS, RN, and Shobha Malviya, MD, (2003) at S. Mott Children's Hospital, University of Michigan Health System.

3.9.2 SCORING PROCEDURE

The minimum obtainable score for each category was zero and maximum score was 2. The total score was between 0-10.

3.9.3 SCORE INTERPRETATION

Based on the score the pain response is graded as follows:

SCORE	INTERPRETATION
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

3.10 TESTING OF THE TOOL

VALIDITY

The tool was validated by 2 paediatrician and 3 paediatric nursing experts, Suggestions were considered. All the experts have their consensus and then the tool was finalized.

RELIABILITY

The reliability of the tool was tested using Crohnbach's Alpha method with a sample size of 10 The internal consistency reliability was found with value r = 0.75. The tool was considered highly reliable.

3.11 PILOT STUDY

Pilot study was conducted at Pediatric outpatient department, Institute of Child Health & Research Centre, Government Rajaji Hospital, Madurai from 16.09.2013 to 21.09.2013. 10 infants (5 in experimental groups and 5 in control groups) who fulfilled the inclusion criteria were selected using purposive sampling technique. A brief self introduction was given to mothers of all the subjects. The purpose of the study explained to their mothers and consent was obtained from the mothers.

Interview method was used to collect the baseline variables. For infants in the experimental group oral glucose (25% oral dextrose) of 1 ml was administered with dropper 2 seconds prior to the invasive procedures. Then the investigator assessed the level of pain with CRIES pain scale (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness). For infants in the control group no intervention was given. Then the investigator assessed the level of pain with CRIES pain scale (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness). Finding of the pilot study revealed that the study was feasible and practicable to conduct the main study. The data collection for the main study was planned to be done by excluding the subjects included in the pilot study.

3.12 DATA COLLECTION PROCEDURE

The main study was conducted for a period of six weeks from 01.10.2013 to 15.11.13 at Pediatric outpatient department, Institute of Child Health & Research Centre, Government Rajaji Hospital, Madurai. Infants who fulfilled the inclusion criteria were selected using purposive sampling technique. A brief self introduction was given to mothers of all the subjects. The purpose of the study was explained to

their mothers. Both verbal and written consent was obtained from the mothers. Interview method was used to collect the baseline variables.

During the first week 10 samples (5 - experimental groups and 5 - control groups) were selected using purposive sampling technique. For infants in the experimental group oral glucose (25% oral dextrose) of 1 ml was administered with dropper 2 seconds prior to the invasive procedures. Then the investigator assessed the level of pain with CRIES pain scale (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness). For infants in the control group no intervention was given. Then the investigator assessed the level of pain with CRIES pain scale (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness).

During the second, third, fourth, fifth and sixth week the same procedure was repeated for 10 samples (5 in experimental group and 5 in control group).

3.13 PLAN FOR DATA ANALYSIS

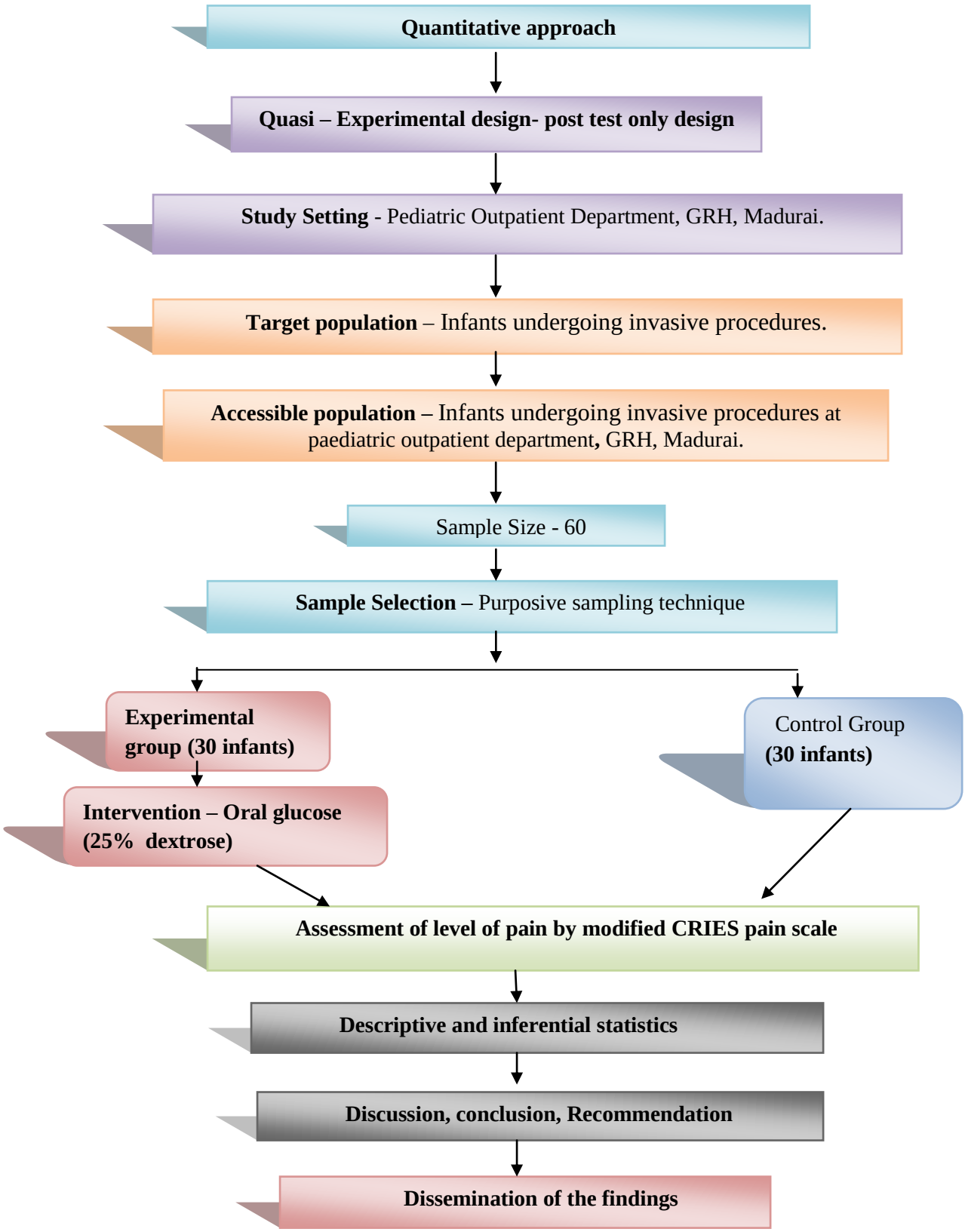
Data collected were analyzed using both descriptive and inferential statistics.

1. Base line variables were analyzed using frequency and percentage distribution.
2. Mean, Standard deviation were used to analyze the pain level of infants both in experimental and in the control group.
3. Unpaired‘t’ test was used to evaluate the effectiveness of oral glucose on pain during invasive proceduress.
4. Chi square test was used to find the association between the pain level of infants in experimental group and base line variables.

3.14 PROTECTION OF HUMAN RIGHTS

The proposed study was conducted after the approval of dissertation committee of College of Nursing, Madurai Medical College, Madurai. In order to protect the human rights ethical committee approval obtained from Ethical Committee, Madurai medical college, Madurai. The research proposal was approved by the Director, Institute of Child health & Research centre, Government Rajaji Hospital, Madurai. Both verbal and written consent was obtained from all the subjects and the data collected was kept confidential. The possible benefit of participating in the study was explained to all the subjects. Reassurance was given to the study subjects that confidentiality and privacy was maintained.

3.15 SCHEMATIC REPRESENTATION OF RESEARCH STUDY



CHAPTER – IV

DATA ANALYSIS AND INTERPRETATION

Analysis is the process of organizing and synthesizing the data so as to answer research questions and test hypothesis. (Suresh K. Sharma). This chapter deals with the analysis and interpretation of data collected from the 60 infants those who were undergoing invasive procedures. The data have been analyzed and presented under the following headings.

SECTION: A

Base line characteristics of the experimental and control group

This analysis has been done to find out the frequency and percentage distribution of demographic variables such as Age, sex, term, weight of the child, type of delivery, type of family, place of residence, mothers literacy level, birth order, and type of feeding.

SECTION: B

Assess the effectiveness of oral glucose on pain during invasive proceduress of infants for experimental group.

Pain has been analyzed in four degrees (No pain, Mild pain, Moderate pain, severe pain) for the experimental and control group during Immunisation in frequency and percentage.

SECTION: C

Compare the pain level of infants during invasive procedures in both experimental and control group.

Comparison of degree of pain in experimental and control group has been done by mean score and its significance by statistical test.

SECTION: D

Association between pain level of infants among experimental group with selected base line variables

Base line variables of experimental group have been analyzed in association with pain level during intra muscular injection.

SECTION – A

BASE LINE CHARACTERISTICS OF EXPERIMENTAL AND CONTROL GROUP

Frequency and percentage distribution of Base line variable of infants in experimental and control group:

n=60

S.NO	BASE LINE VARIABLES	EXPERIMENTAL GROUP n=30		CONTROL GROUP n=30	
		f	%	f	%
1.	Age (in months)				
	a) 0-3	7	23	8	27
	b) 3-6	5	17	7	23
	c) 6-9	9	30	8	27
	d) 9-12	9	30	7	23
2.	Male	17	57	16	53
	Female	13	43	14	47
3.	Term of baby at birth				
	a) Pre term	0	0	0	0
	b) Full-term	23	77	26	87
	c) Post term	7	23	4	13
	d) SGA	0	0	0	0
4.	Weight of the child				
	a) Less than 3kg	15	50	6	20
	b) Between 3kg to 6 kg	15	50	12	40
5.	Type of delivery				
	a) Normal	17	57	20	67
	b) Cesarean	12	40	10	33
	c) Forceps	1	3	0	0
	d) Vaccum	0	0	0	0

S.NO	BASE LINE VARIABLES	EXPERIMENTAL GROUP n=30		CONTROL GROUP n=30	
		f	%	f	%
6.	Family type				
	a) Nuclear	19	63	16	53
	b) Joint family	11	37	14	47
	c) Separated	0	0	0	0
7.	Place of residence				
	a) Urban	12	40	5	17
	b) Rural	8	27	15	50
	c) Semi urban	0	0	0	0
	d) Sub urban	10	33	10	33
8.	Mothers				
	a) Illiterate	1	3	4	13
	b) Primary	6	20	10	33
	c) High school	8	27	4	13
	d) Higher secondary	7	23	7	23
	e) Graduate	8	27	5	17
9.	Birth order				
	a) 1	12	40	15	50
	b) 2	11	37	8	27
	c) 3	7	23	7	23
10.	Feeding				
	a) Breast feeding	12	40	15	50
	b) Artificial feeding	0	0	0	0
	c) Both	10	33	5	17
	d) Weaning	8	27	10	33

The above table represents that, the age group among experimental group were in the age group of 0-3 months, 7(24%) were in the age group of 3-6 months, 5(17%) were in the age group of 6-9 months, and 9(30%) were in the age of 9-12 months are 9(30%). In control group 8(27%) were in the age group of 0-3 months, 7(24%) were in the age group of 3-6 months, 8(27%) were in the age group of 6-9 months, and 7(24%) were in the age group of 9-12 months. With the view of sex, experimental group 17(57%) were males, and 13(43%) were females. In control group 16(53%) were males and 14(47%) were females. Among the term of baby in experimental group are full term 23(77%), there is no preterm babies, and few postdated 7(23%) and also small for gestational age is none. In control group, majority of the baby are full term 26(87%), there were no preterm and small for gestational age infants, whereas, postdated delivery are rare of 4(13%).

While accounting the weight of the child in experimental group, no infants had their weight between 6 kg to 9 kg and also no baby weighed more than 9 kg, among the weight less than 3 kg it was 15(50%) and also same 15(50%) of the baby weighed between 3 kg to 6 kg, However, In control group, there were no infants weighed more than 9 kg, the weight less than 3 kg were 6(20%) the weight between 3 kg to 6 kg were 12(40%) and between 6 kg to 9 kg it was 12(40%).

Considering according to type of delivery in experimental group the infants born through normal vaginal delivery were 17(57%), whereas, cesarean 12(40%), through forceps delivery 1(3%) and there is no vaccum delivery. In control group majority of the infant were born by normal vaginal delivery 20(67%), through cesarean 10(33%) and no delivery occurred through forceps and vaccum delivery.

In experimental group the family types are nuclear is dominating about 19(63%), joint family 11(37%), and there is no separated family. Compared with experimental group, the control group have nuclear type family of 16(53%), joint family 14(47%) and also no separated family. The place of residence in experimental group in urban 12(40%), rural 8(27%), there were no place of residence in semi urban whereas in sub urban there were 10(33%). In control group the place of residence in urban 5(17%), majority constitute from rural 15(50%), no one from semi urban and in suburban 10(33%).

Among the mother's literacy rate in experimental group, illiterate are less of 1(3%), the mother's with primary education are 6(20%), in high school 8(27%), in higher secondary 7(24%), graduates are 8(27%), on notifying with control group the mother's literacy level are, illiterate 4(13%), more number of mother's had primary education of 10(33%), in high school 4(13%), in higher secondary 7(23%), whereas in graduates 5 (17%).

With the birth order of the baby in experimental group, first birth order are 12(40%), in second birth order 11 (37%), while according to third birth order is of 7 (23%). The birth order in control group, first birth order contributes majority of 15(50%), according to second 8(27%), in third order of birth 7(23%). Finally, in experimental group, the type of feeding, majority constitutes breast feeding of 12(40%), no infant is fed with artificial feeding, few are fed with weaning of 10(33%), but another few babies are given both weaning and breast milk of 8(27%). In control group, breast feeding were given for 15(50%), weaning for 10(33%), both for 5(17%), no artificial feeding are given.

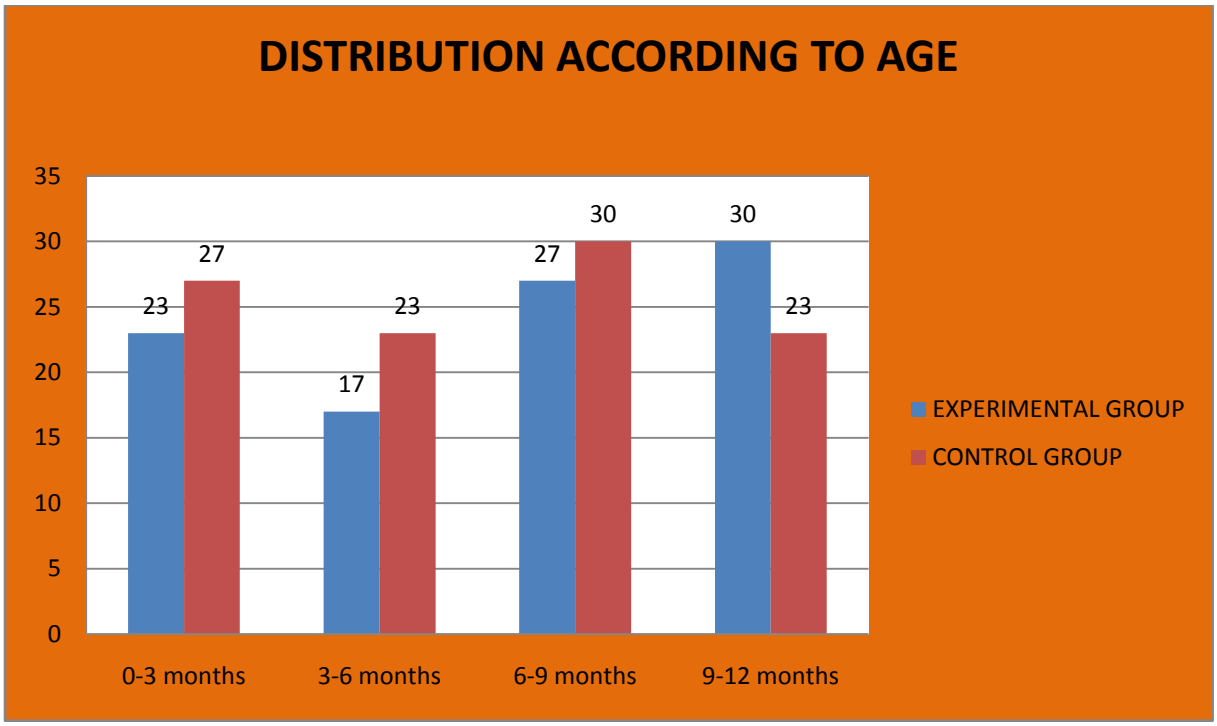


Fig 3; Percentage distribution of infants according to age.

The above table represents that, in experimental group the age group of 6-9 months, and 9(30%) were in the age of 9-12 months are 9(30%) representing more. In control group majority 8(27%) were in the age group of 0-3 months, and 8(27%) were in the age group of 6-9 months.

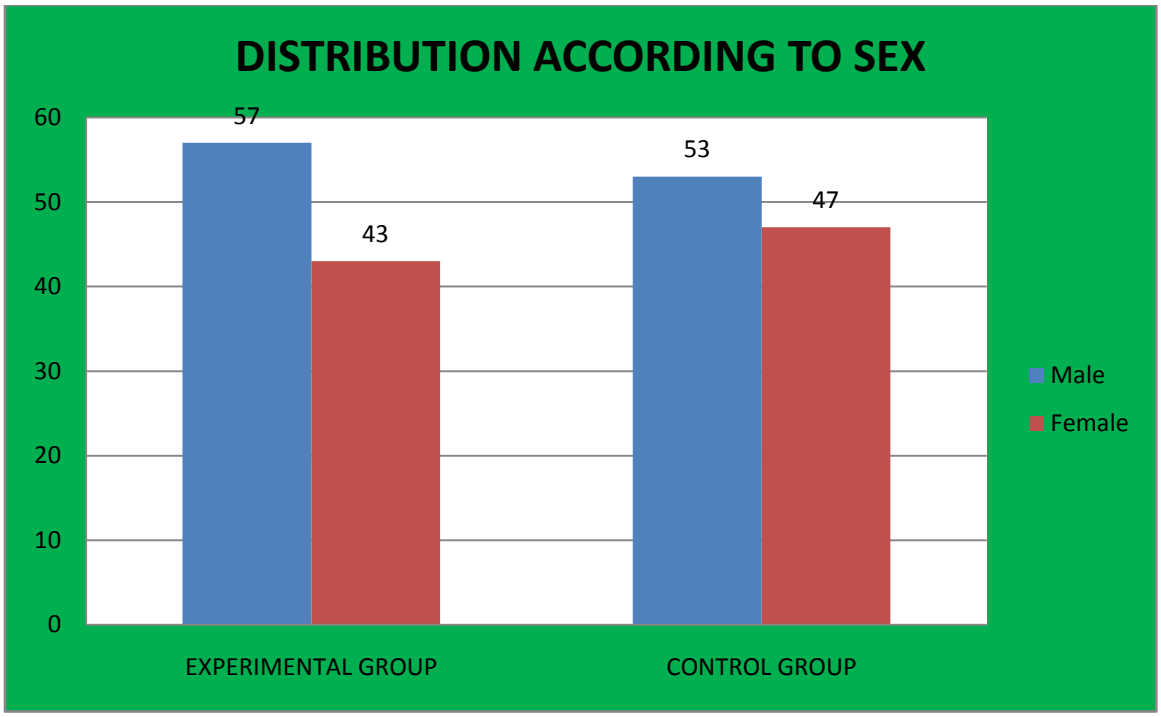


Fig 4; Percentage distribution of infants according to sex.

With the view of sex, experimental group 17(57%) were males, and 13(43%) were females. In control group 16(53%) were males and 14(47%) were females.

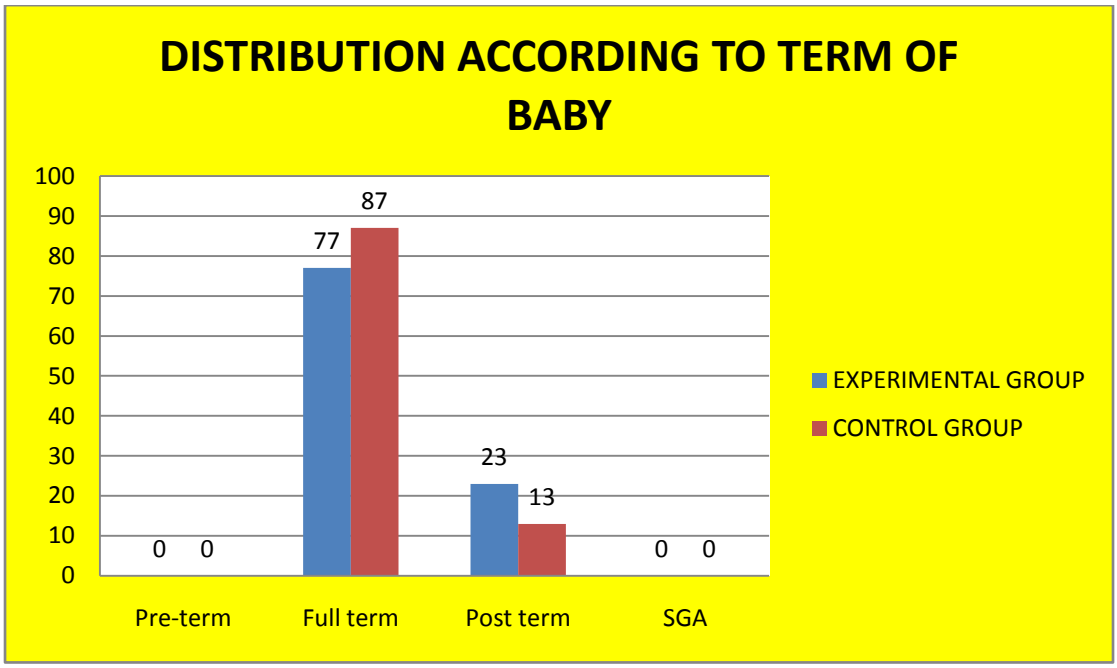


Fig 5; Percentage distribution of infants according to term of baby.

Among the term of baby in experimental group are full term 23(77%), there is no preterm babies, and few postdated 7(23%) and also small for gestational age is none. In control group, majority of the baby are full term 26(87%), there were no preterm and small for gestational age infants, whereas, postdated delivery are rare of 4(13%).

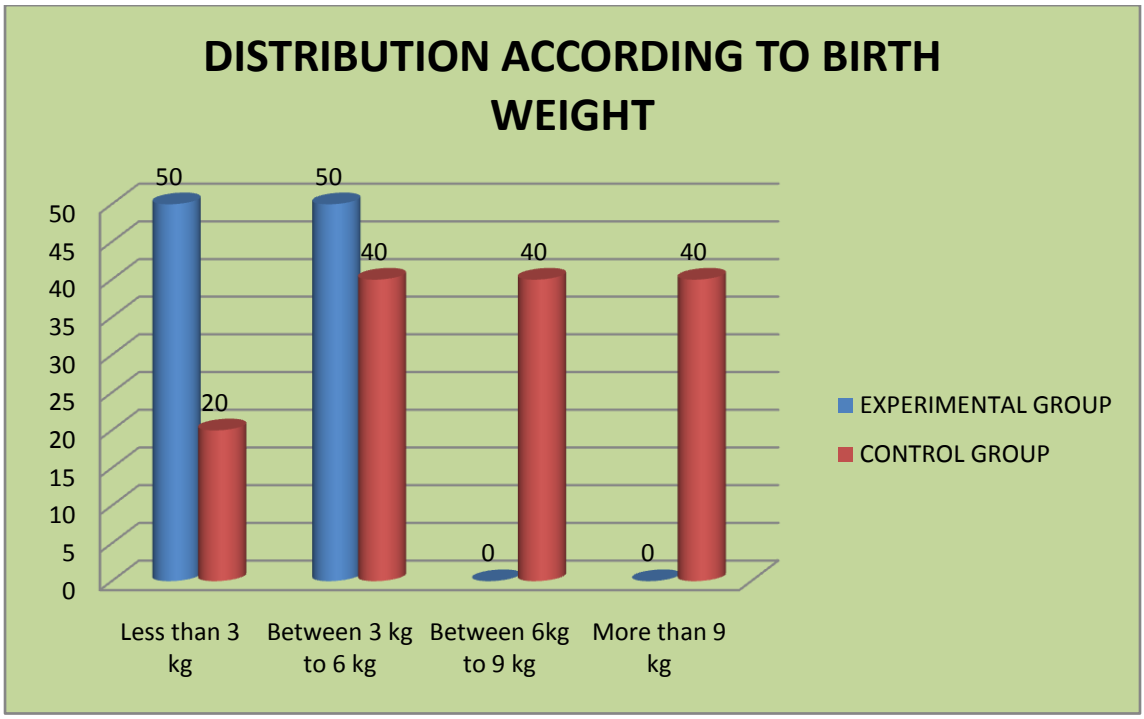


Fig 6;Percentage distribution of infants according to weight of the child.

While accounting the weight of the child in experimental group, the weight less than 3 kg it was 15(50%) and also same 15(50%) of the baby weighed between 3 kg to 6 kg, However, In control group, the weight less than 3 kg were 6(20%) the weight between 3 kg to 6 kg were 12(40%) and between 6 kg to 9 kg it was 12(40%).

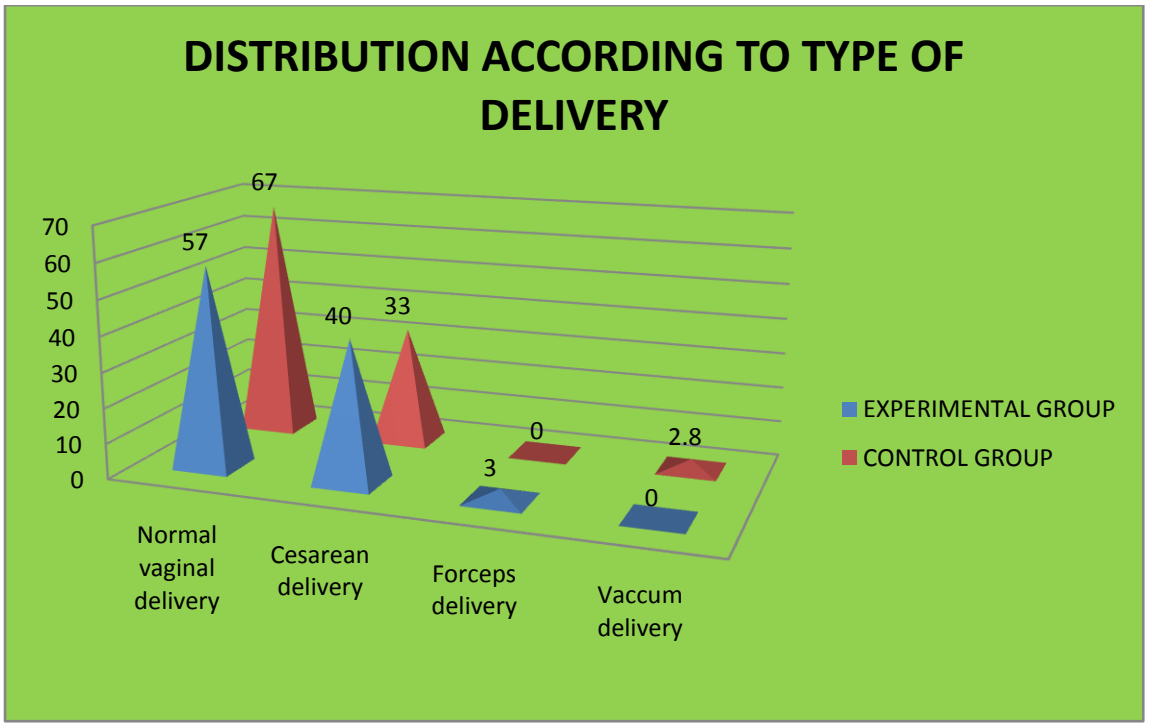


Fig 7;Percentage distribution of infants according to type of delivery.

Considering according to type of delivery in experimental group the infants born through normal vaginal delivery were 17(57%), whereas, cesarean 12(40%), through forceps delivery 1(3%) and there is no vaccum delivery. In control group majority of the infant were born by normal vaginal delivery 20(67%), through cesarean 10(33%) and no delivery occurred through forceps and vaccum delivery.

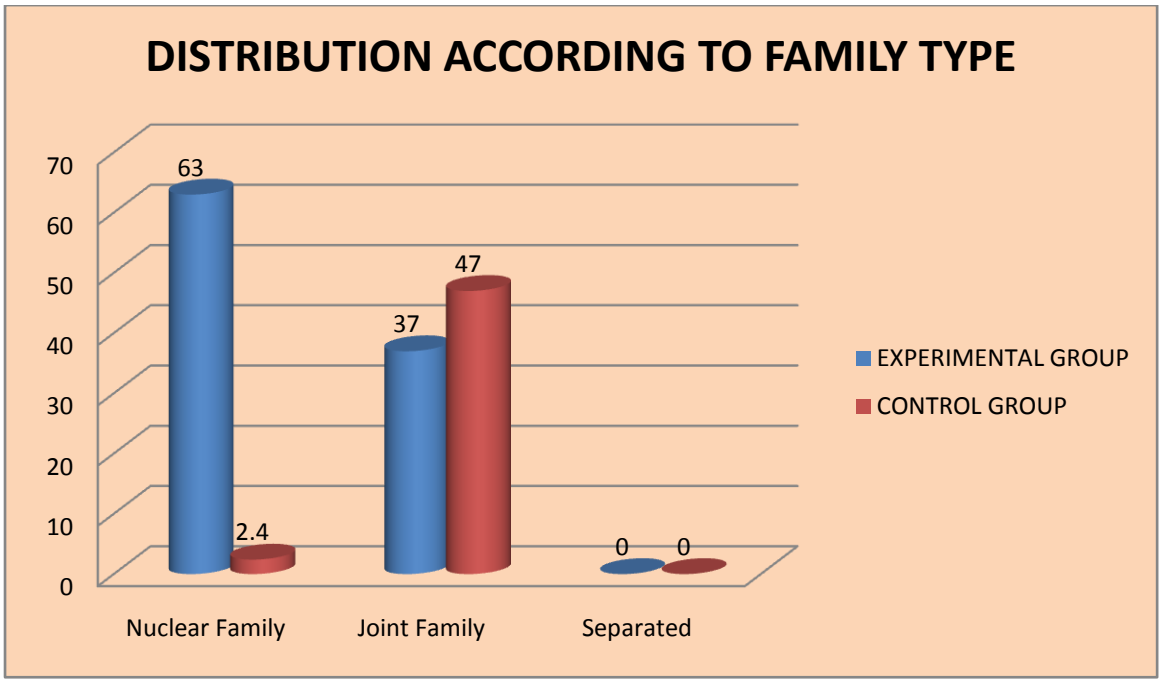


Fig 8;Percentage distribution of infants according to family type.

In experimental group the family types are nuclear is dominating about 19(63%), joint family 11(37%), and there is no separated family. Compared with experimental group, the control group have nuclear type family of 16(53%), joint family 14(47%) and also no separated family.

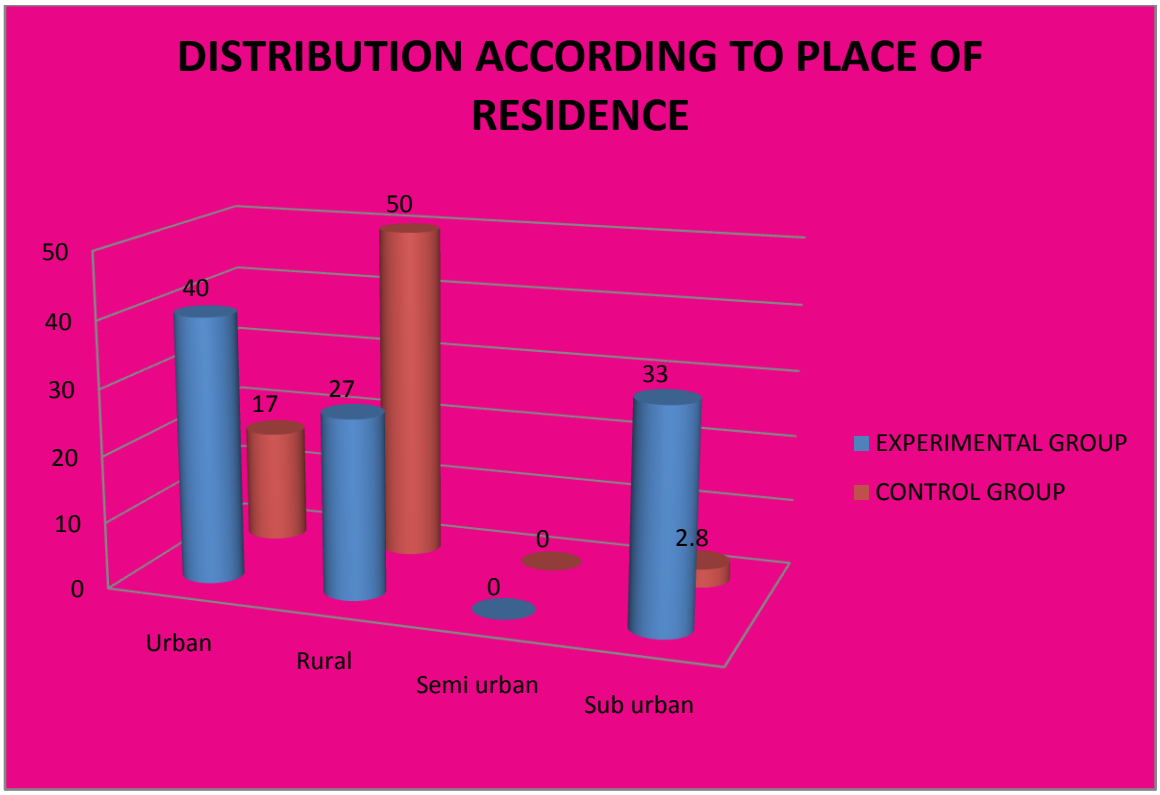


Fig 9;Percentage distribution of infants according to place of residence.

The place of residence in experimental group in urban 12(40%), rural 8(27%), there were no place of residence in semi urban whereas in sub urban there were 10(33%). In control group the place of residence in urban 5(17%), majority constitute from rural 15(50%), no one from semi urban and in suburban 10(33%).

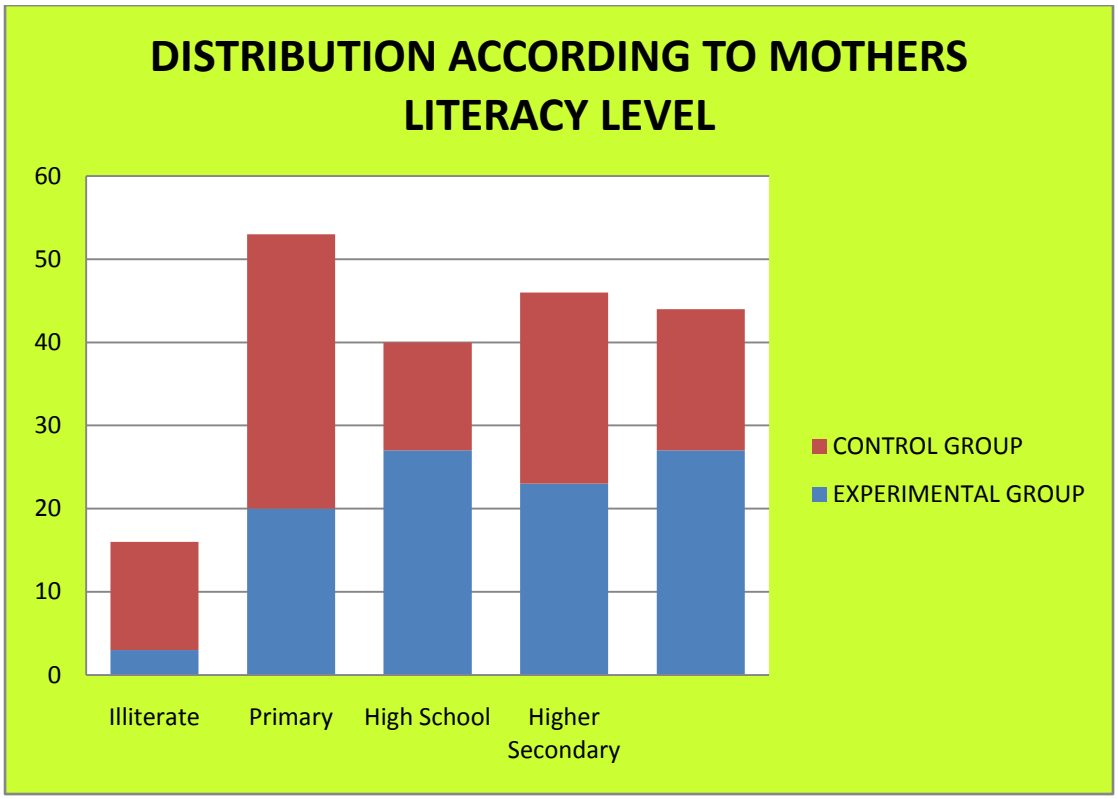


Fig 10; Percentage distribution of infants according to mothers literacy level.

Among the mother's literacy rate in experimental group, illiterate are less of 1(3%), the mother's with primary education are 6(20%), in high school 8(27%), in higher secondary 7(24%), graduates are 8(27%), on notifying with control group the mother's literacy level are, illiterate 4(13%), more number of mother's had primary education of 10(33%), in high school 4(13%), in higher secondary 7(23%), whereas in graduates 5 (17%).

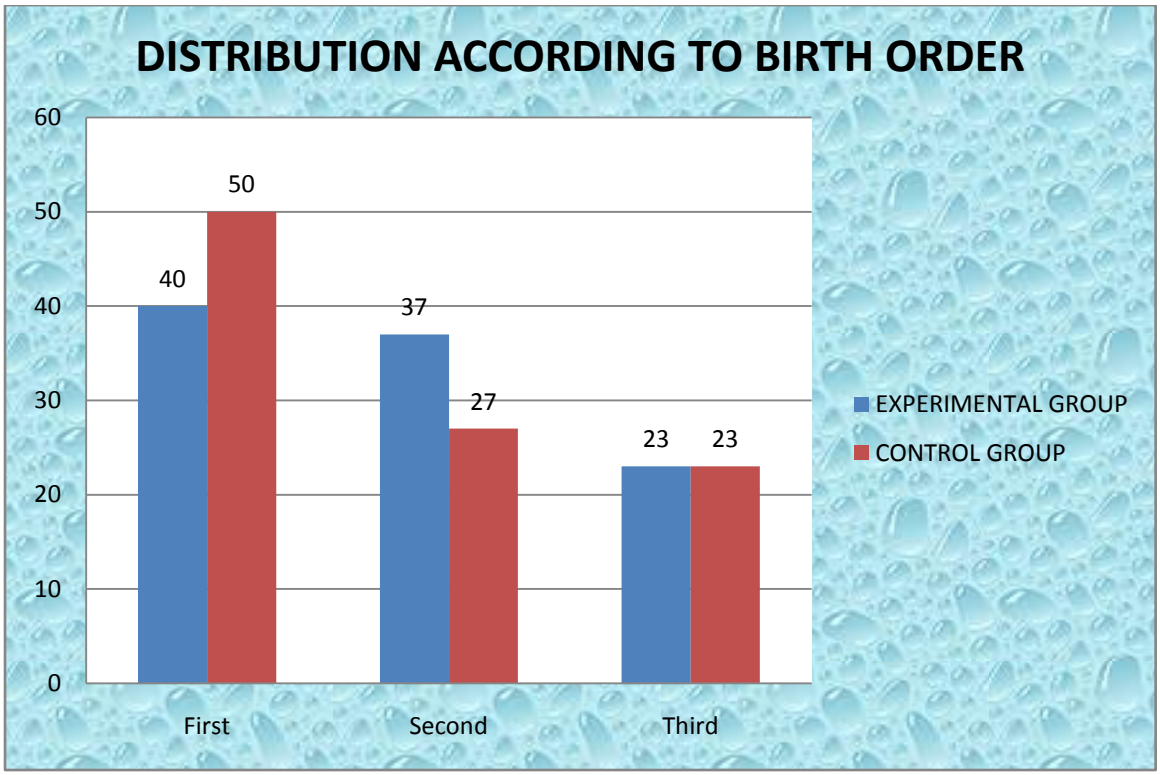


Fig 11; Percentage distribution of infants according to birth order.

With the birth order of the baby in experimental group, first birth order are 12(40%), in second birth order 11 (37%), while according to third birth order is of 7 (23%). The birth order in control group, first birth order contributes majority of 15(50%), according to second 8(27%), in third order of birth 7(23%).

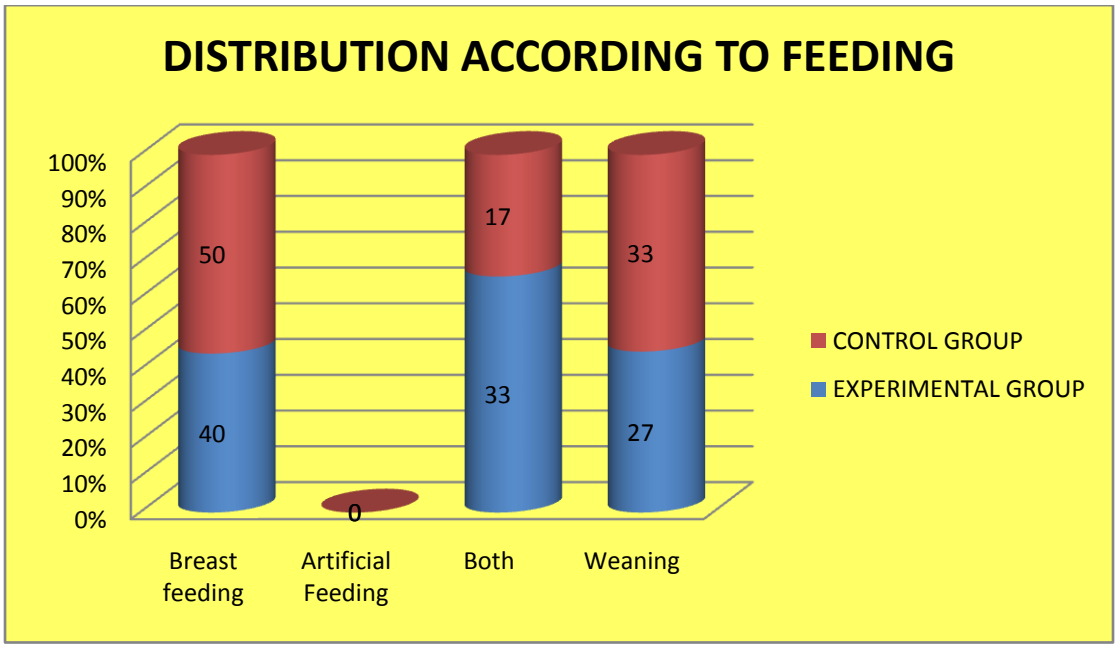


Fig 12;Percentage distribution of infants according to feeding.

In experimental group, the type of feeding, majority constitutes breast feeding of 12(40%), no infant is fed with artificial feeding, few are feeding with weaning of 9(30%), but another few babies are given both weaning and breast milk of 9(30%). In control group, breast feeding were given for 15(50%), weaning for 10(33%), both for 5(17%), no artificial feeding are given.

SECTION: B

PAIN LEVEL OF INFANTS DURING INVASIVE PROCEDURES AMONG EXPERIMENTAL AND CONTROL GROUP

TABLE – 2

Frequency and percentage data of infants during invasive proceduress among experimental and control group

n=60

LEVEL OF PAIN	EXPERIMENTAL GROUP n=30		CONTROL GROUP n=30	
	f	**%**	f	%
No pain (0)	-	-	-	-
Mild pain (1-3)	10	33	-	-
Moderate pain (4-6)	20	67	5	17
Severe pain (7-10)	-	-	25	83

This table represents the pain level of infants in experimental group, majority of the infants had moderate pain of 20(67%) and few infant had mild pain of 10(33%). Severe pain was absent for the infants in experimental group. In control group, majority of the infants had severe pain of 25(83%) and few infants experienced moderate pain of 5(17%) during invasive proceduress.

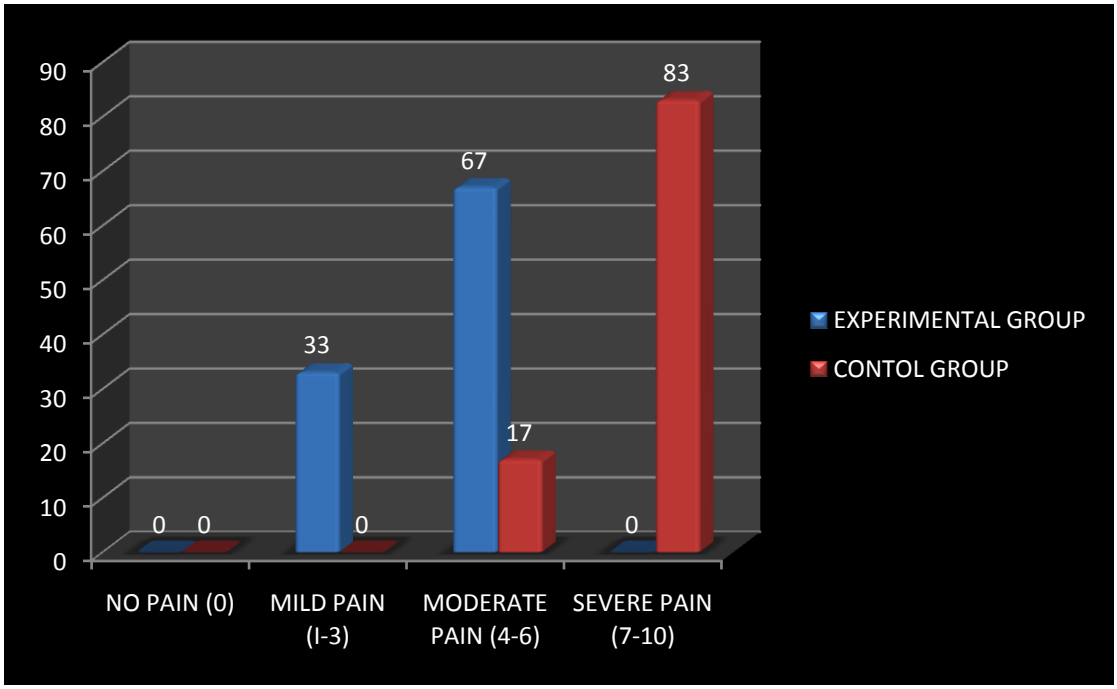


Fig 13: Percentage distribution of pain levels during invasive proceduress of experimental group and control group.

Comparing with the control group, experimental group have moderate pain of 67% and mild pain of 33% whereas, control group have severe pain of 83% and moderate pain of 17%.

TABLE – 3

MEAN PAIN SCORE AND STANDARD DEVIATION OF INFANTS DURING INVASIVE PROCEDURES AMONG EXPERIMENTAL AND CONTROL GROUP

S. No	GROUP	TOTAL SCORE			EFFECTIVENESS OF MEAN %
		MEAN	SD	MEAN %	
1.	Experimental group	4.26	1.11	43	33
2.	Control group	7.63	0.76	76	

The above table describes the mean and standard deviation score of infants with pain level. The mean score of pain level among the experimental group is 4.26 and in the control group is 7.63 whereas the standard deviation among the experimental group is 1.11, in the control group is 0.76, the mean percentage level were in control group 76% was higher than the mean percentage 43% in experimental group. Effectiveness of mean percentage is 33.

SECTION: C

COMPARISON OF PAIN LEVEL IN EXPERIMENTAL AND CONTROL GROUP.

TABLE – 4

Unpaired "t"-test to assess the effectiveness of Oral glucose

n=60

PAIN SCORE	EXPERIMENTAL GROUP		CONTROL GROUP		't'-value	'p'-value
	Mean	SD	Mean	SD		
Overall score	4.26	1.11	7.63	0.76	15.9	0.000***

***P<0.005, Highly significant

The above table indicates that overall mean score of experimental and control group during invasive proceduress. The control group mean (7.63) is higher than the experimental group mean (4.26) of the infants. The obtained 't' value is 15.9, significant at p<0.005 level. This concludes that experimental group experienced less pain than control group. Hence, administration of oral glucose had effect on reducing the pain during invasive proceduress.

SECTION: D

ASSOCIATION BETWEEN PAIN RESPONSE OF INFANTS AMONG EXPERIMENTAL GROUP AND SELECTED BASE LINE VARIABLES

TABLE – 5

n=30

Baseline variables	Mild Pain		Moderate Pain		$\chi 2$	P value
	f	%	f	%		
Age (in months)						
a) 0-3	3	10	4	13	7.05	0.03
b) 3-6	3	10	2	7		
c) 6-9	4	13	5	17		
d) 9-12	0	0	9	30		
Sex						
a) Male	6	20	11	37	0.18	0.32
b) Female	4	13	9	30		
Term of baby						
a) Pre term	0	0	0	0	6.90	0.021
b) Full-term	8	27	15	49		
c) Post term	2	7	5	17		
d) SGA	0	0	0	0		
Weight of the child						
a) Less than 3kg	6	20	6	20	7.43	0.032
b) Between 3kg to 6 kg	4	13	14	47		
c) Between 6 kg to 9 kg	0	0	0	0		
d) more than 9 kg	0	0	0	0		
Type of delivery						
a) Normal	5	17	12	40	0.82	0.06
b) Cesarean	5	17	7	23		
c) Forceps	0	0	1	3		
d) Vaccum	0	0	0	0		

Baseline variables	Mild Pain		Moderate Pain		$\chi 2$	P value
	f	%	f	%		
Family type						
a) Nuclear	7	23	12	40	9.73	0.04
b) Joint family	3	10	8	27		
c) Separated	0	0	0	0		
Place of residence						
a) Urban	4	13	8	27	10.77	0.08
b) Rural	4	13	4	13		
c) Semi urban	0	0	0	0		
d) Sub urban	2	7	8	27		
Mothers literacy						
a) Illiterate	0	0	1	3	14.56	0.06
b) Primary	4	13	2	7		
c) High school	0	0	8	27		
d) Higher secondary	3	10	4	13		
e) Graduate	3	10	5	17		
Birth order						
a) 1	3	10	9	29	11.05	0.04
b) 2	5	17	6	20		
c) 3	2	7	5	17		
Feeding	6	20	6	20	14.67	0.03
a) Breast feeding	0	0	0	0		
b) Artificial feeding	2	7	7	23		
c) Both	2	7	6	20		
d) Weaning						

This table depicts that there is significant association between the pain response of infants and baseline variables in age, weight of the child, and feeding of baby during invasive procedures among experimental group.

CHAPTER- V

DISCUSSION

This chapter discusses the findings of this study. The findings of the present study are compared and contrasted with those of similar studies. The present study was undertaken with an objective to assess the effectiveness of oral dextrose on pain response of infants undergoing invasive procedures in paediatric outpatient department, Institute of Child Health & Research centre, GRH, Madurai.

Oral glucose was effective in reducing symptoms associated with pain from venipuncture in term infants7-8 but the analgesic effects of oral glucose in premature infants has not yet been reported in literature. The aim of this study was to prove the effectiveness of orally administered glucose during invasive procedures in infants. In a series of studies, oral sucrose or glucose has been used to alleviate pain reactions during blood sampling, by heel stick or venupuncture. Other interventions such as non-nutritive sucking skin-to-skin contact and swaddling have also been proposed as means of reducing pain during blood sampling in newborns.

The use of oral sucrose has been the most extensively studied pain intervention in infants. More than 150 published studies relating to sweet-taste-induced calming and analgesia in human infants have been identified, of which 100 (65%) include sucrose. With only a few exceptions, sucrose, glucose, or other sweet solutions reduced pain responses during commonly performed painful procedures in diverse populations of infants up to 12 months of age. Sucrose has been widely recommended for routine use during painful procedures in newborn and young infants, yet these recommendations have not been translated into consistent use in clinical practice.

BASELINE CHARACTERISTIC OF EXPERIMENTAL AND CONTROL GROUP

The age group among experimental group, were in the age group of 0-3 months, 7(24%) were in the age group of 3-6 months, 5(17%) were in the age group of 6-9 months, and 9(30%) were in the age of 9-12 months are 9(30%). In control group 8(27%) were in the age group of 0-3 months, 7(24%) were in the age group of 3-6 months, 8(27%) were in the age group of 6-9 months, and 7(24%) were in the age group of 9-12 months. With the view of sex, experimental group 17(57%) were males, and 13(43%) were females. In control group 16(53%) were males and 14(47%) were females.

Among the term of baby in experimental group are full term 23(77%), there is no preterm babies, and few postdated 7(23%) and also small for gestational age is none. In control group, majority of the baby are full term 26(87%), there were no preterm and small for gestational age infants, whereas, postdated delivery are rare of 4(13%). While accounting the weight of the child in experimental group, no infants had their weight between 6 kg to 9 kg and also no baby weighed more than 9 kg, among the weight less than 3 kg it was 15(50%) and also same 15(50%) of the baby weighed between 3 kg to 6 kg, However, In control group, there were no infants weighed more than 9 kg, the weight less than 3 kg were 6(20%) the weight between 3 kg to 6 kg were 12(40%) and between 6 kg to 9 kg it was 12(40%).

Considering the type of delivery in experimental group the infants born through normal vaginal delivery were 17(57%), whereas, cesarean 12(40%), through forceps delivery 1(3%) and there is no vaccum delivery. In control group majority of the infant were born by normal vaginal delivery 20(67%), through cesarean 10(33%)

and no delivery occurred through forceps and vaccum delivery. In experimental group the family types are nuclear is dominating about 19(63%), joint family 11(37%), and there is no separated family. Compared with experimental group, the control group have nuclear type family of 16(53%), joint family 14(47%) and also no separated family.

The place of residence in experimental group in urban 12(40%), rural 8(27%), there were no place of residence in semi urban whereas in sub urban there were 10(33%). In control group the place of residence in urban 5(17%), majority constitute from rural 15(50%), no one from semi urban and in suburban 10(33%). Among the mother's literacy rate in experimental group, illiterate are less of 1(3%), the mother's with primary education are 6(20%), in high school 8(27%), in higher secondary 7(24%), graduates are 8(27%), on notifying with control group the mother's literacy level are, illiterate 4(13%), more number of mother's had primary education of 10(33%), in high school 4(13%), in higher secondary 7(23%), whereas in graduates 5 (17%).

With the birth order of the baby in experimental group, first birth order are 12(40%), in second birth order 11 (37%), while according to third birth order is of 7 (23%). The birth order in control group, first birth order contributes majority of 15(50%), according to second 8(27%), in third order of birth 7(23%). Finally, in experimental group, the type of feeding, majority constitutes breast feeding of 12(40%), no infant is fed with artificial feeding, few are fed with weaning of 10(33%), but another few babies are given both weaning and breast milk of 8(27%). In control group, breast feeding were given for 15(50%), weaning for 10(33%), both for 5(17%), no artificial feeding are given.

FINDINGS BASED ON THE OBJECTIVES:

THE FIRST OBJECTIVE WAS TO ASSESS THE PAIN RESPONSE OF INFANTS DURING INVASIVE PROCEDURES AMONG EXPERIMENTALGROUP.

The pain response of infants in experimental group, majority of the infants had moderate pain of 20(67%) and few infant had mild pain of 10(33%). Severe pain was absent for the infants in experimental group. In control group, majority of the infants had severe pain of 25(83%) and few infants experienced moderate pain of 5(17%) during invasive proceduress.

Thus the H1 There will be significant difference in pain response among infants in control group and experimental group.

THE SECOND OBJECTIVE WAS TO COMPARE THE PAIN RESPONSE DURING INVASIVE PROCEDURESS OF INFANTS BETWEEN CONTROL GROUP AND EXPERIMENTAL GROUP.

The mean score of pain response among the experimental group is 4.26 and in the control group is 7.63 whereas the standard deviation among the experimental group is 1.11, in the control group is 0.76, the mean percentage level were in control group 76% was higher than the mean percentage 43% in experimental group. Effectiveness of mean percentage is 33.

The findings of study in Reduction of Neonatal Pain Following Administration of 25% Lingual Dextrose conducted by Nimbulkar Orally administered, sweet tasting solutions are commonly used in management of

neonatal pain. They conducted a double-blind randomized control trial in infants admitted to Neonatal Intensive Care Unit of Shri Krishna Hospital, Karamsad-Gujarat-India, of lingual administration of 25% dextrose vs. no intervention, to evaluate reduction of pain following oropharyngeal infant feeding tube insertions. Pain was assessed using Premature Infant Pain Profile score. Almost all the patients in the control group (98%) experienced moderate-to-severe pain as compared with the intervention group (71%). Mean Premature Infant Pain Profile score was statistically significantly lower in the intervention group (8.21) as compared with control group (10.31). ($p < 0.001$, 95% CI 1.090-3.102). Lingual 25% dextrose is an effective analgesic for relieving pain during orogastric tube insertion.

The other study also conducted to assess the Oral glucose solution as pain relief in newborns: results of a clinical trial. It was long believed that newborns could not experience pain. As it is now documented that newborns have all the necessary systems to perceive pain, pain management can no longer be ignored. The objective of this study is to investigate which concentration of glucose is most effective in reducing pain for venipuncture in the newborn. This double-blind clinical trial of 304 newborns was conducted on a maternity and neonatal ward (neonatal medium intensive care unit). During at least 1 month, one of the four selected solutions (10, 20, 30% glucose, and placebo) was administered orally, 2 minutes before the venipuncture was performed. The pain from the skin puncture was scored using a validated pain scale (the "CRIES Pain Scale"). This study showed a significantly lower average pain score in the 30 percent glucose group (3.99) when compared with the placebo group (8.43). The average pain scores in the 20 percent glucose group (5.26) and the 10 percent glucose group (5.92) were also significantly lower than those in the placebo group. Oral administration of 2 mL of 30

percent glucose 2 minutes before the venipuncture provides the most effective pain reduction in newborns.

The overall mean score of experimental and control group during invasive proceduress. The control group mean (7.63) is higher than the experimental group mean (4.26) of the infants. The obtained 't' value is 15.9, significant at $p<0.005$ level. This concludes that experimental group experienced less pain than control group. Hence, administration of oral glucose had effect on reducing the pain during invasive proceduress.

THE THIRD OBJECTIVE WAS TO FIND THE ASSOCIATION BETWEEN PAIN RESPONSE AND THE SELECTED BASELINE VARIABLES AMONG INFANTS IN EXPERIMENTAL GROUP.

There was a significant association between the pain response of infants and baseline variables in age, birth weight, and feeding of baby during invasive procedures among experimental group.

This result is compatible with the study done by Dilen B (2010) conducted a study to assess Oral glucose solution as pain relief in newborns: results of a clinical trial. It was long believed that newborns could not experience pain. As it is now documented that newborns have all the necessary systems to perceive pain, pain management can no longer be ignored. The objective of this study is to investigate which concentration of glucose is most effective in reducing pain for venipuncture in the newborn. This double-blind clinical trial of 304 newborns was conducted on a maternity and neonatal ward (neonatal medium intensive care unit). During at least 1 month, one of the four selected solutions (10, 20, 30% glucose, and

placebo) was administered orally, 2 minutes before the venipuncture was performed. The pain from the skin puncture was scored using a validated pain scale (the "CRIES Pain Scale"). This study showed a significantly lower average pain score in the 30 percent glucose group (3.99) when compared with the placebo group (8.43). The average pain scores in the 20 percent glucose group (5.26) and the 10 percent glucose group (5.92) were also significantly lower than those in the placebo group. Oral administration of 2 mL of 30 percent glucose 2 minutes before the venipuncture provides the most effective pain reduction in newborns.

This is study is also accordant with the study done by Pandy M (2012) conducted a study on the efficacy of repeated versus single dose sucrose**,** to reduce pain from routine heel stick procedure in pre term infants. Infants (n=48) in the first week of life with mean gestational age of 31 weeks received 0.05ml of 24% sucrose solution or sterile water orally thrice, i.e., (1) 2 min prior to actual lancing of the heel; (2) Just prior to lancing, and (3) 2 min after lancing. The single dose group received sucrose for the first dose and water for the second and third dose; the repeated dose group received sucrose 3 times and placebo group received only water. Pain was measured by Premature Infant Pain Profile (PIPP) scores for five times on a 30 second interval after lancing. Infants with sucrose orally have lower PIPP scores when compared to infants with water and infants in the repeated dose had lower scores than infants with single dose.

Thus the H2: There will be significant association between pain response and the selected baseline variables among infants in experimental group.

CHAPTER - VI

SUMMARY, CONCLUSION AND RECOMMENDATIONS

This chapter details about the summary of the study findings, conclusion, implications and recommendations.

SUMMARY OF THE STUDY:

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. The experience of pain is always subjective. Hence, verbalization of nociceptive sensation is the gold standard for assessment of pain. Since infants cannot verbalize their pain, the recognition and management of pain in newborn babies is still suboptimal in neonatal intensive care units. Studies have documented that babies born at less than 32 weeks of gestation are exposed to 10–15 painful procedures each day during the first few weeks of life, and in almost 80% no treatment for pain relief is offered. Oral glucose was effective in reducing symptoms associated with pain from invasive procedures in term infants7-8. The aim of this study was to compare the pain reducing effect of orally administered glucose with that of sterile water during venipuncture in newborns.

The investigator conducted a study to assess the effectiveness of oral glucose on pain response among infants during invasive procedures.

The objectives of the study were:

- To assess the pain responses of infants during invasive proceduress for both the control group and experimental group.

- To assess the effectiveness of oral glucose on pain during invasive proceduress of infants for experimental group.
- To compare the pain response of infants during invasive procedures in experimental group and control group.
- To find the association between pain response in experimental group and control group with the selected infants.

The tested hypothesis of the study was:

H_1- There will be significant difference in pain response between administrations of oral glucose with usual standard technique during invasive proceduress.

H_2- There will be significant association between oral glucose and reduction of pain among infants during invasive procedures with the selected baseline variables.

The study was conducted in paediatric outpatient department, Institute of Child Health & Research Centre, GRH, Madurai. The research approach used in the study was a quantitative approach and design was quasi-experimental design. The sampling technique was purposive sampling technique. The total sample size was 60; among that 30 were in experimental group, 30 were in control group. Standardized CRIES (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness) pain scale used for measurement of pain. The content validity and reliability was obtained prior from the study. Following that, a pilot study was conducted and it found that, the tool was feasible and practicable The data collection was done for a period of four weeks from 1.10.2013 to 15.11.13. 25% Oral dextrose of 1ml was administered with the help of dropper to the experimental group. First selected the infant and administered 25% Oral dextrose of 1ml with the help of

dropper prior 2 seconds of administering injection. Then pain score was assessed by CRIES (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness). For the control group nothing was administered, after injection, the pain score was assessed by CRIES (Cry, Requirement of oxygen, Increase in Vital Signs, Expression of face, Sleeplessness).The data were analyzed by descriptive and inferential statistics.

MAJOR FINDINGS OF THE STUDY

- The age group among experimental group was in the age group of 0-3 months, 7(24%).
- With the view of sex, experimental group 17(57%) were males, and 13(43%) were females. In control group 16(53%) were males and 14(47%) were females.
- Among the term of baby in experimental group are full term 23(77%), there is no preterm babies.
- While accounting the birth weight of the baby in experimental group, no infants are born less than 2 kg, majority of the baby had the weight between 2-2.5 kg 15(50%).
- Considering according to type of delivery both in experimental and control group normal vaginal delivery was major as 17(57%) & 20(67%),
- In experimental group the family types are nuclear is dominating about 19(63%), joint family 11(37%), and there is no separated family. Compared with experimental group, the control group have nuclear type family of 16(53%), joint family 14(47%) and also no separated family.

- The place of residence in experimental group constitute in urban 12(40%), whereas in control group majority constitute from rural 15(50%), no one from semi urban.
- Among the mother's literacy rate in experimental group, more mothers were educated such as, in high school 8(27%), in higher secondary 7(24%), graduates are 8(27%).
- In experimental group and control group majority constitutes breast feeding of 12(40%) and 15(50%), no infant was fed with artificial feeding,
- The mean score of pain level among the experimental group is 4.26 and in the control group is 7.63.
- Since the mean score of control group (7.63) is higher than the experimental group mean (4.26) of the infants, and also the obtained 't' value is 15.9, significant at $p<0.005$ level, the experimental group experience less pain than control group.
- Analyzing statistically there is no significant association between the pain level of infants and demographic variables such as Age, sex, term, birth weight, type of delivery, type of family, place of residence, mothers literacy level, birth order, and type of feeding**.**

CONCLUSION:

The study concluded that 25% oral dextrose is effective in reducing pain in infants. Neopharmocological management is an effective means of reduction of procedural pain in infants. It can also be used as a routine with standard care so that infant's behavioral responses can be managed in an effective way. Nurses can facilitate the comfort of their patients by using pain management techniques for infants.

IMPLICATIONS OF THE STUDY

The study has implications in nursing practice, nursing education, nursing research and nursing administration.

6.3.1 NURSING PRACTICE

Health personnel should be trained to recognize and assess pain for infants well being and pain control. Early recognition and pain management of infants are essential not only in the procedural time but also throughout hospitalization. Hospital should use pain protocol for assessment and management of pain. Pain management in infants are now considered as a key area in pediatric nursing, as a nonpharmocological management are inexpensive. So it can be easily used by nurses.

NURSING EDUCATION

In paediatric nursing curriculum, pain is an important topic. Curriculum should provide opportunity for the students to care for infants experiencing pain and this will increase the skills of students in the assessment and management of pain. To help the student to develop knowledge and skill in assessment and management of responses to pain, the faculty needs orientation in various methods. The use of non-pharmocological pain relieving intervention such as oral dextrose administration is one of the most important aspects to be included in the clinical nursing practice. Students should also be taught to use pain assessment tools.

NURSING ADMINISTRATION

Nursing administration may be involved in policy making and budgeting. Written guidelines should be provided to standardize and improve documentation related to pain assessment. Pain score should be documented and readily available to all the members of health care team. Nursing administrator should make a policy in using nonpharmocolgical techniques along with routine care. They should develop nursing practice standards, protocols and manuals of pain assessment and pain management in infants which shoul include nonpharmacological techniques as an important strategy to relieve pain for neonates. Administrator should ensure the availability of a variety of non pharmacological management in procedural pain and supervise the usage.

NURSING RESEARCH

Pain and its consequences can prolong the hospital stay, which will increase the patient acre cost. The main goal of nursing research should be to improve patient acre. Procedural pain is an important aspect and nonpharmocological techniques are an effective means for reducing the pain in infants associated with procedural pain. Further research in this area wills help the nurse to find out other effective nonpharmocological techniques to reduce pain, which is easily and locally available. Emphasis should be given to the utilization of the research findings. Appropriate utilization of the research helps nurses to make evidence based decision regarding care of the children.

RECOMMENDATIONS

Based on the findings of the present study, the recommendations offered for future research are:

- Similar study can be conducted on a large sample.
- Similar study can be conducted on other age groups as per the age related distraction techniques.
- Further research can be conducted by using other non-pharmacological measures like use of breast milk, EMLA cream and different dilution of dextrose.
- A blind folded study can be recommended to reduce bias while assessing pain.

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APPENDIX – I

PART – A

RESEARCH TOOL

BASELINE VARIABLES

1. Age of the baby
    a. 0 to 3 months
    b. 3 to 6 months
    c. 6 to 9 months
    d. 9 to 12 months.

2. Sex of the child
    a. Male
    b. Female

3. Term of the baby at birth
    a. Preterm
    b. Full term
    c. Post dated
    d. Small for gestational age

4. Weight of the child
    a. Less than 3 kg
    b. Between 3 kg to 6 kg
    c. Between 6 kg to 9 kg
    d. More than 9 kg

5. Type of delivery
    a. Normal vaginal delivery with episiotomy
    b. Cesarean delivery
    c. Forceps delivery
    d. Vaccum delivery

6. Type of family
    a. Nuclear family
    b. Joint family.
    c. Separated

7. Place of residence
    a. Urban
    b. Rural
    c. Semi urban
    d. Sub urban

8. Mothers literacy level
    a. Illiterate
    b. Primary education
    c. High school
    d. Higher secondary
    e. Graduate and above.

9. Birth order
    a. First child
    b. Second child
    c. Third and above

10. Type of feeding
    a. Breast feeding
    b. Artificial feeding
    c. Both
    d. Weaning foods.

SECTION – II

MODIFIED CRIES PAIN SCALE

Put a tick (✓) mark on suitable

S.No	CATEGORY	SCORE	CHILD SCORE
I.	**CRYING**		
	No cry	0	
	Cry, easily consolable	1	
	High pitch cry and inconsolable	2	
II	**REQUIRES OXYGEN FOR SATURATION**		
	No oxygen required	0	
	Requires <30% of oxygen	1	
	Requires > 30% of oxygen	2	
III.	**INCREASED VITAL SIGNS**		
	Both Heart rate & BP not changed	0	
	Heart rate & BP is increased <20% of baseline	1	
	Heart rate & BP is increased >20%	2	
IV	**EXPRESSION (FACIAL)**		
	No grimace present	0	
	Grimace alone present	1	
	Grimace with grunt is present	2	
V	**SLEEPLESS (half an hour state of the child)**		
	Continuous sleep	0	
	Awakens at frequent intervals	1	
	Child has been constantly awaken	2	

APPENDIX – I (B)

SECTION II

SCORING PROCEDURE

The minimum obtainable score for each category was zero and maximum score was 2. The total score was between 0-10.

SCORE INTERPRETATION

Based on the score the pain response is graded as follows:

SCORE	INTERPRETATION
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

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1. குழந்தை வயது

    ஒரு. 0 3 மாதங்கள்

    ப. 3 முதல் 6 மாதங்கள்

    சி. 6 முதல் 9 மாதங்கள்

    டி. 9 முதல் 12 மாதங்கள்.

2. குழந்தை பாலியல்

    ஒரு. ஆண்

    ப. பெண்

3. குழந்தை கால

    ஒரு. குறைகால

    ப. முழு கால

    சி. பின் தேதியிட்ட

    டி. கர்ப்பகால வயது சிறு

4. குழந்தை பிறப்பு எடை

    ஒரு. குறைவான 3 கிலோ.

    ப. 3 முதல் 6 கிலோ வரை

    சி. 6 முதல் 9 கிலோ வரை

    டி. மேற்பட்ட 9 கிலோ

5. விநியோக வகை

ஒரு. புண்டவாய் திறப்பு சாதாரண யோனி விநியோகம்

ப. அறுவைசிகிச்சை பிரசவம்

சி. ஃபோர்செப்ஸ் விநியோகம்

டி. Vaccum விநியோகம்

6. குடும்ப வகை

ஒரு. தனிக்குடும்பம்

ப. கூட்டு குடும்பம்.

சி. பிரிந்து வாழ்பவர்

7. வசிக்கும் இடம்

ஒரு. நகர்ப்புற

ப. கிராமிய

சி. நகர்ப்புற பகுதி

டி. துணை நகர்ப்புற

8. தாய்மார்கள் கல்வியறிவு நிலை

ஒரு. எழுதப்படிக்க தெரியாத

ப. முதன்மை கல்வி

சி. உயர்நிலை பள்ளி

டி. மேல்நிலைக்கல்வி

இ. பட்டதாரி மற்றும் மேலே.

9. பிறப்பு வரிசை

ஒரு. முதல் குழந்தை

ப. இரண்டாவது குழந்தை

சி. மேலே மூன்றாவது மற்றும்

10. உணவு வகை

ஒரு. தாய் பாலூட்டல்

ப. செயற்கை (முறை) ஊட்டல்

சி. இரண்டு

டி. உணவுகள் தாயிடமிருந்து பிரித்தல்.

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§.ÜÆ	§č╓	†¡±÷‰	‡•∞č╚≈∫ †¡±÷‰
I	**ÄÓč╓**		
	Ä•»µč╟	0	
	ÄÓ≤, ÜÀ¡µ Äč╜ ¡±ü‰ØùÈøÍ≤	1	
	€∆≠‰ ÄÓ≤ Äč╜ ¡±ü‰ØùÈø°ČÊ	2	
II	**Ć╚č╟╒±ü‰≤ √¢Čú§ČÍ»∫ Ä¶Ì**		
	√¢Čú§ČÍć╚č╟≈µč╟	0	
	Êç% ©‡≤ ‡č╣§Č® √¢Čú§ČÍ	1	
	Êç%©‡≤ ć╜∪ü≠õ √¢Čú§ČÍ	2	
III	**Ä¡ó±üø°Č® Ñ≈¥ûČø≈∫ Ä¶Ìó┌**		
	Ç¢ØùĆ╓Č¡±Ë †∪Ò≤ ÇÎù°Êø±Ë †Čß»µč╟	0	
	ÇÎù°Êø±Ë †∪Ò≤ Ç¢ØùĆ╓Č¡±Ëèç% ©‡≤ ‡č╣§Č® Ä¶Ì	1	
	ÇÎù°Êø±Ë †∪Ò≤ Ç¢ØùĆ╓Č¡±Ë èç%©‡≤ Ä¡ó†Č®	2	
IV	**Èó±üČ§č╤ (Èó≤)**		
	Èó±üČ§č╤ Çµč╟	0	
	Èó±üČ§č╤ †≠‰≤ Ñ┌¶Ê	1	
	Èó±üČ§č® †∪Ò≤ È©óµ Ñ┌¶Ê	2	
V	**Ñß©ó∱∫č╜ (‡•∞č╚≈∫ Äč╞†¿ ć╚¢ ¬č╟)**		
	Ć╚Čõ¥∞Ê ˇ™‡ùµ	0	
	‡Ã±√≠õ ć╚¢ Çč╕≈čõć╜ »…Øùµ	1	
	»…Øù ¬č╟	2	

APPENDIX - B

Ref. No. 9101/E4/3/2013 **Govt Rajaji Hospital,**
Madurai-20. Dated: 20.09.2013

Institutional Review Board I independent Ethics Committee,
Dr. N. Mohan, MS., F.LC.S F.A.I.S.,
Dean, Madurai Medical College &
Govt Rajaji Hospital, Madurai 625020. **Convener.**

Sub: Establishment-Govt. Rajaji Hospital. Madurai-20-
Ethics committee-Meeting Minutes- for August 2013
Approved list -regarding.

The Ethics Committee meeting of the Govt. Rajaji Hospital, Madurai was held on 08.08,2013, Wednesday at 10.00 am to 12.00.pm at the Anesthesia Seminar Hail, Govt. Rajaji Hospital, Madurai. The following members of the committee have attended the meeting.

I Dr. V, Nagarajan, M.D., D.M (Neuro) Ph: 0452-2629629 Cell.No 9843052029	Professor of Neurology (Retired) D.No.72, Vakkil New Street, Simmakkal, Madurai -1	Chairman
2. Dr.Mohan Prasad. MS M.Ch Cell,No.9843050822 (Oncology)	Professor & H.O.D of Surgical Oncology(Retired) D.No.72, West Avani Moola Street. Madurai -1	Member Secretary
3. Dr. I. Jeyaraj, M.S... (Anatomy) Cell.No 9566211947	Director & Professor Institute of Anatomy /V,P Madurai Medical College	Member
4. Dr. Parameswari M.D (Pharmacology) Cell.No.9994026056	Director of Pharmacology Madurai Medical College	Member
5. Dr.S. Vadivel Murugan, MD., (Gen.Medicine) Cell.No 9566543048	Professor of Medicine Madurai Medical College	Member
6. Dr.S. Meenakshi Sundaram, MS (Gen.Surgery) Cell.No 9842138031	Professor & H.O.D of Surgery i/c Madurai Medical College	Member
7. Miss, Mercy Immaculate Rubalatha, MA., Med,, Cell. No. 9367792650	50/5, Corporation Officer's quarters, Gandhi Museum Road, Thamukam, Madurai-20	Member
8. Thiru. .Pala. .Ramasamy , BA.,B.L.,Cell.No 9842165127	Advocate, D.No,72.Palam Station Road, Sellur, Madurai -2	Member
9. Thiru. P.K.M. Chelliah,B.A Cell.No 9894349599	Businessman, 21 Jawahar Street. Gandhi Nagar, Madurai-20	Member

The following Projects were approved by the committee

S.No	Name of P.G	Course	Name of the Project	Remarks
1.	Saranya.P	M.Sc Nursing, College of Nursing, Madurai Medical College	A study to assess the effectiveness of oral glucose on pain response among infants during invasive procedures, in pediatric outpatient department, Government Rajaji Hospital, Madurai.	Approved

Please note that the investigator should adhere the following: She / He should get a detailed informed consent from the patients/participants and maintain it confidentially.

1.She / he should carry out the work without detrimental to regular activities as well as without extra expenditure to the institution or to Government,

2. She/he should inform the institution Ethical Committee, in case of any change of study procedure, site and investigation or guide.

3. She / He should not deviate the area of the work for which applied for Ethical clearance, She / He should inform the JEC immediately, in case of any adverse events or Serious adverse reactions.

4, She / He should abide to the rules and regulations of the institution,

5. She / He should complete the work within the specific period and if any Extension of time is required He / She should apply for permission again and do the work,

6. She / He should submit the summary of the work to the Ethical Committee on Completion of the work.

7. She / He should not claim any funds from the institution while doing the work or on completion.

8. She / He should understand that the members of IEC have the right to monitor the work with prior intimation.

Member Secretary **Chairman**
Ethical Committee

DEAN/Convenor
Govt. Rajaji Hospital,
Madurai- 20.

20/9/13

To
The above Applicants
-thro. Head of the Department concerned

APPENDIX - C

LETTER SEEKING PERMISSION FOR CONDUCTING THE STUDY

From

Saranya.P

M.Sc (N) I year student (Br- II. Child Health Nursing)

College of Nursing

Madurai Medical College, Madurai - 20

To

The Director,

Institute of Child Health and Research Centre,

Government Rajaji Hospital

Madurai Medical College,

Madurai.

Through

The Proper Channel

Respected Sir,

Sub : College of Nursing, Madurai Medical College, Madurai – M.Sc.(N) I year Child Health Nursing Student – Permission for conduct dissertation study- Institute of Child Health and Research Centre, GRH – request – regarding.

****

As per the Indian Nursing Council and the Tamilnadu Dr. M.G.R. Medical University curriculum requirement all branches of M.Sc Nursing candidates are required to conduct a dissertation study for the partial fulfillment of the P.G Degree course in their respective departments.

I have selected a study topic "**Effectiveness of oral glucose on reduction of pain response among infants during invasive procedures in paediatric outpatient department, at Government Rajaji hospital, Madurai** for my dissertation study; I would like to select patients from the above department.

I assure that I will not interfere with the routine activities of the department.

Hence I Kindly request you to consider my requisition and permit me to conduct the study.

Thanking you,

Yours obediently,

DATE : 07/5/13

Madurai

R. JEYASUNDARI M.Sc., (N) M.Phil., PGDHA., M.A., (Pub. Admin) (Socio) M.A., (JMC) Clinical Lecturer / Tutior in Nursing COLLEGE OF NURSING MADURAI MEDICAL COLLEGE Madurai-625 020.

(Co-ordinator & HOD in CHILD HEALTH NSG)

(Saranya.P)

DIRECTOR INSTITUTE OF CHILD HEALTH & RESEARCH CENTRE GOVT. RAJAJI HOSPITAL

Content Validation Certificate

I hereby certify that I have validated the research study of Saranya.P II year M.Sc Nursing Student of College of Nursing, Madurai Medical College, Madurai who is undertaking the following study:

"Effectiveness of oral glucose on reduction of pain response among infants during invasive procedures in paediatric outpatient department, Government Rajaji hospital, Madurai"

Place: madurai

Date: 13/9/13

R. Jothilakshmi

Signature of the Expert

Reader,
Sacred Heart nursing
College, madurai

Designation and Address

CERTIFICATE OF TAMIL EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation **"EFFECTIVENESS OF ORAL GLUCOSE ON PAIN RESPONSE AMONG INFANTS DURING INVASIVE PROCEDURE, GOVERNMENT RAJAJI HOSPITAL, MADURAI"** done by Mrs. Saranya.P, M.Sc., Nursing II year student, College of Nursing, Madurai Medical College, Madurai has been edited for Tamil language appropriateness.

Name : K.R. Krishnaram

Designation : Asst. Prof.

Institution : Sourashtra College, Madurai-4

K.R. Krishnaram

Signature

Dr. K.R. KRISHNARAM, M.A., M.Phil., P.h.D.,
Assistant Professor, Department of Tamil,
Sourashtra College,
Madurai-625004.

CERTIFICATE OF ENGLISH EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation **"EFFECTIVENESS OF ORAL GLUCOSE ON PAIN RESPONSE AMONG INFANTS DURING INVASIVE PROCEDURE, GOVERNMENT RAJAJI HOSPITAL, MADURAI"** done by Mrs. Saranya.P M.Sc., Nursing II year student, College of Nursing, Madurai Medical College, Madurai has been edited for English language appropriateness.

Name : M. MARIMUTHU

Designation : B.T. ASSISTANT (ENGLISH)

Institution : PANCHAYAT UNION MIDDLE SCHOOL
MAITTANPATTI

Signature

M. MARIMUTHU, M.A., M.Phil., B.Ed.,
B.T. Assistant
P.U.M. School,
Maittan Patti, Kalligudi (Union)
Madurai (Dt)-625 701.

Content Validation Certificate

I hereby certify that I have validated the research study of Saranya.P II year M.Sc Nursing Student of College of Nursing, Madurai Medical College, Madurai who is undertaking the following study:

"Effectiveness of oral glucose on reduction of pain response among infants during invasive procedures in paediatric outpatient department, Government Rajaji hospital, Madurai"

Place: Mana madurai

Date: 12/9/13

Signature of the Expert

Designation and Address

Associate Professor
Maha College of Nursing
Vaan puram
Mana madurai

APPENDIX – D

CONTENT VALIDATION

Content Validation Certificate

I hereby certify that I have validated the research study of Saranya.P II year M.Sc Nursing Student of College of Nursing, Madurai Medical College, Madurai who is undertaking the following study:

"Effectiveness of oral glucose on reduction of pain response among infants during invasive procedures in paediatric outpatient department, Government Rajaji hospital, Madurai"

Place:

Date:

INSTITUTE OF CHILD HEALTH & RESEARCH CENTRE
11 SEP 2013
MADURAI
GOVT. RAJAJI HOSPITAL

11.9.13

DIRECTOR I/C
INSTITUTE OF CHILD HEALTH &
RESEARCH CENTRE
GOVT. RAJAJI HOSPITAL
MADURAI - 625 020

Signature of the Expert

Designation and Address

Content Validation Certificate

I hereby certify that I have validated the research study of Saranya.P II year M.Sc Nursing Student of College of Nursing, Madurai Medical College, Madurai who is undertaking the following study:

"Effectiveness of oral glucose on reduction of pain response among infants during invasive procedures in paediatric outpatient department, Government Rajaji hospital, Madurai"

Place: Madurai

Date: 11.9.13.

11/9/13

Signature of the Expert

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Date: 30.08.2013

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APPENDIX – E

ஒப்புதல் அறிக்கை

எனக்கு இந்த ஆய்வைப்பற்றிய முழு விவரம் விளக்கமாக எடுத்துரைக்கப்பட்டது. இந்த ஆய்வில் பங்குபெறுவதில் உள்ள நன்மைகள் மற்றும் தீமைகள் பற்றி நான் புரிந்துக்கொண்டேன். நான் இந்த ஆய்வில் தானாகவே முன்வந்து பங்கு பெறுகிறேன். மேலும் எனக்கு இந்த ஆய்வில் இருந்து எந்த நேரமும் விலகிக்கொள்ள முழு அனுமதி வழங்கபட்டுள்ளது. என் குழந்தையின் சிகிச்சை ஆவணங்களைப் பார்வையிட்டு அதில் உள்ள விவரங்களை ஆய்வில் பயன்படுத்திக் கொள்ள அனுமதி அளிக்கிறேன். என்னுடைய பெயர் மற்றும் அடையாளங்கள் ரகசியமாக வைத்துக்கொள்ளபடும் என்றும் எனக்கு உறுதியாளிக்கப்பட்டுள்ளது.

இப்படிக்கு,

APPENDIX - F

PHOTOGRAPHS

The Investigator Takes Oral Glucose (25% Dextrose) In Dropper

The investigator administers oral glucose prior to invasive procedure with dropper

The investigator assess the pain score level with modified CRIES scale.